Technology and Equipment Committee Meeting

August 29, 2007

Radiation Oncology Services - Linear Accelerators Material

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Radiation Oncology Services - Linear Accelerators

Material Related To

Linac Petition-1: Moses Cone Health System

MOSES CONE HEALTH SYSTEM

Petition for Adjusted Need Determination
Proposed 2008 State Medical Facilities Plan
Addition of Need for a Linear Accelerator with Stereotactic Radiosurgery
Capabilities in Linear Accelerator Service Area 12

Moses Cone Health System (MCHS) submits this petition to the State Health Coordinating Council (SHCC) requesting an adjusted need determination in Linear Accelerator Service Area 12 (Guilford and Rockingham Counties) to add need for one (1) new piece of linear accelerator equipment with stereotactic radiosurgery (SRS) capabilities.

Background

Stereotactic radiosurgery is an advanced form of radiation therapy that combines stereotactic (three dimensional) localization with multiple cross-fired beams from a collimated radiation source from outside the body. This technology allows delivery of a high dose of radiation to a treatment site while keeping the exposure of healthy tissue at a safe level.[1] As a result, larger and more effective doses of radiation can be administered in fewer treatment sessions to a more precise location. SRS can be used to treat tumors that cannot be treated with traditional radiation therapy or surgical techniques because of their location, number, size, shape or proximity to vital tissues or organs, or because of the age or health of the patient.

As will be discussed subsequently, SRS is establishing a unique role as a highly effective therapy for a growing number of tumor sites. Despite this role, the Certificate of Need Section has determined that SRS is a form of linear accelerator equipment, and this petition is submitted in the context of this determination.

[1] Image-Guided Radiosurgery in the Treatment of Spinal Metastases, Murphy, at al. Neurosurgical Focus. 2001 Dec 15; 11(6):e6.

Rationale for Adjusted Need Request

An adjusted need determination for an SRS-capable linear accelerator is essential to providing state-of-the-art care to the patient population of Linear Accelerator Service Area 12 that currently lacks access to this technology within the defined service area, has a sufficient patient population base to support SRS (greater than 500,000 residents), yet cannot currently acquire SRS technology without negatively affecting existing capacity for established radiation therapy services. The following discussion presents the rationale for approving the requested adjusted need determination.

Clinical Applications

Stereotactic radiosurgery clinical applications are both proven and expanding. SRS technology has been used for more than 30 years, and over 100,000 patients have been treated worldwide. In its earliest form, SRS was used to treat only intracranial (head and neck) tumors or lesions via a Gamma Knife. This system, however, utilizes a rigid metal frame that is fixed to the patient's skull, immobilizing the head so that damage to the healthy tissue surrounding the tumor is minimized when the radiation is delivered. Advancements in technology that can provide SRS via a linear accelerator now enable the delivery of high doses of radiation to intracranial tumors without a metal head frame or to extracranial tumors, such as spine, lung, prostate, liver, and pancreas, while maintaining and even improving submillimeter accuracy to target the tumor or lesion.

Linear accelerators with SRS capabilities are manufactured by Elekta, Novalis, Accuray, Tomotherapy and Varian. This petition does not attempt to highlight one manufacturer over another; rather, this petition seeks to add SRS capabilities to the complement of radiation therapy services provided to residents of Linear Accelerator Service Area 12 without diminishing existing capabilities for traditional radiation therapy.

SRS is one of the fastest-growing areas of oncologic radiation therapy. Sg2, a health care intelligence firm, forecasts that SRS for the treatment of intracranial cancer will grow 108% over the next ten (10) years and SRS for extracranial cancer treatment will grow an astonishing 255% over the next ten (10) years. Intracranial utilization of SRS will increase as the technology is used for patients with multiple or recurrent brain lesions once thought to be untreatable, as clinical efficacy improves for non-cancer indications, such as functional disorders and acoustic neuromas, as incidence of brain metastases increases due to improved survival rates for other primary cancers, and as public awareness and interest in receiving state-of-the-art care increases. Additional factors affecting an increase in utilization of SRS for extracranial applications include growing clinical efficacy of extracranial applications and non-cancer indications, such as benign tumors, increased cancer incidence as a result of an aging population and treatment advances that extend patient longevity, and increasing public awareness and interest in receiving state-of-the-art care.[2]

Physician support for the addition of SRS equipment in Service Area 12 is well established; this support underscores the need for the proposed adjusted need determination. Because SRS is capable of treating both intra- and extracranial tumors, neurosurgeons, oncologists, and radiation oncologists all support the need for availability of SRS for a variety of clinical applications, as evidenced by support letters presented in Exhibit I.

Geographic Access

Current access to intra and extracranial SRS technology for patients living in Service Area 12 is limited. Table 1 lists the current providers of stereotactic radiosurgery in North Carolina and the associated SRS technology.

[2] Sg2 Clinical Intelligence. Stereotactic Radiosurgery: Strategies for Success. 2006.

Table 1
Current North Carolina SRS Providers

Hospital/Facility and City	SRS-Capable Equipment	Intra/Extracranial Capability	Number of Procedures FY 2006
NC Baptist Hospital, Winston-Salem	Gamma Knife, SRS Linac	Intracranial Only, Intra and Extracranial	Gamma knife - 285 SRS - 24
Carolinas Medical Center – Northeast, Concord	Cyberknife	Intra and Extracranial	Not operational in FY 2006
Carolinas Medical Center, Charlotte	Novalis SRS Linac	Intra and Extracranial	95
UNC Hospitals, Chapel Hill	SRS Linac	Intra and Extracranial	62
Duke University Hospital, Durham	Varian SRS Linac and Xknife	Intra and Extracranial	115
Memorial Mission Hospital, Asheville	Cyberknife	Intra and Extracranial	272
Pitt County Memorial Hospital/Brody School of Medicine, Greenville	Gamma Knife and CON application pending for Cyberknife to replace existing SRS-capable unit	Intracranial only for Gamma Knife, Intra and extracranial for SRS Linac	Gamma Knife – 105 SRS – 0
Carolina Radiation Medicine, Greenville	Varian SRS Linac	Intra and extracranial	24

Source: Proposed 2008 State Medical Facilities Plan, facility websites, and "Robot Performs Cancer Surgery", News and Observer, July 2, 2007. newsobserver.com.

Exhibit II presents a map depicting the location of these established SRS providers in North Carolina. Several regions within the state experience excessive distances and travel times for stereotactic radiosurgery, often leading to greater hardships on patients and their families and/or the limitation of referral opportunities. This situation is particularly true in Service Area 12, where the size of the resident population warrants more immediate access to SRS technology.

Additionally, existing or planned stereotactic radiosurgery programs have been developed to serve their established service area populations only; they do not include service to other areas with a sufficient population experiencing high utilization of one or more established linear accelerator providers, i.e. Service

Area 12. Hence, these programs are not positioned to meet the significant demand for SRS treatments from the Service Area 12 resident population.

Current SMFP Linear Accelerator Need Methodology

The current methodology used in the SMFP to determine need for additional linear accelerators does not account for the unique technological aspects of SRS. Although the technology is delivered via an SRS-capable linear accelerator, radiosurgery is a longer procedure than traditional radiation therapy. Average treatment time is 140 minutes in duration depending on tumor location and complexity of treatment plan. The treatment plan will require from one to five fractions or treatments to complete the plan. Therefore, the traditional criterion for evaluating radiation therapy capacity, 6,500 Equivalent Simple Treatment Visits (ESTVs) per linear accelerator annually, does not accurately reflect the utilization patterns for radiosurgery. The capacity for stereotactic radiosurgery equipment is approximately 350 patients per year at an average of three (3) treatments per patient and weight of 3.00 or 3,150 ESTVs per year[3]. By comparison, traditional radiation therapy protocols provide thirty (30) or more treatments per patient at approximately fifteen (15) minutes per treatment.

Additionally, the current SMFP linear accelerator need methodology generates need on a service area-wide basis rather than a facility-specific basis. Therefore, a facility that is highly utilized and at or near capacity, yet is part of a service area with other less-utilized facilities, operates at a significant disadvantage. Because the need methodology does not account for individual facility utilization levels, the well-utilized facility is thwarted from obtaining new equipment to meet established trends in patient demand.

The current linear accelerator need methodology also requires a Service Area to meet two (2) of three (3) criteria in order to generate a need. In addition to the utilization standard, one of the criterion states that a Service Area should have a

[3] Sg2 phone conversation and Proposed 2008 State Medical Facilities Plan Table 9F.

population greater than 120,000 per linear accelerator in order to generate need. With a total 2007 population of 547,202 in Service Area 12 and seven (7) existing linear accelerators, population per linear accelerator is 78,172. With projected annual population growth of 1.1% for the Service Area, this criterion will not be met until 2049, well beyond the point at which utilization exceeds capacity. Another criterion can be met when 45% or more of patients come from outside the service area. As an urban area without an academic medical center, it is unlikely that Service Area 12, in particular Moses Cone Health System will trigger this criterion. Therefore, even when utilization of existing linear accelerators reaches capacity, it is unlikely that Service Area 12 will meet either of the other two (2) criterion. It is important to note that MCHS was at 105.0% of capacity for FY 2006 and has been over 96.0% of capacity for the last five (5) years. Therefore, Service Area 12 will need its existing linear accelerators to meet demand for traditional radiation therapy, leaving no excess capacity available to meet demand for SRS.

SRS volume forecasts indicate a sufficient number of patients to justify the use of this equipment to serve the Area 12 resident population. MCHS employed a model developed by Accelitech, a company specializing in business planning and feasibility studies, to project potential SRS patient volume. Using cancer incidence rates, the assumption that 60% of all cancer patients will receive some form of radiation therapy, and the percentage of patients receiving treatment with other forms of radiation, including SRS, MCHS projects that the total number of patients in Area 12 who would be clinically appropriate to receive SRS treatments is 656 in 2007 and 695 in 2012, five years later. Table 2 provides potential SRS volumes for Area 12.

Table 2

Estimated and Projected Area 12 SRS Patients

	2007	2012	# Change	% Change
Estimated Total Potential Patient Volume	656	695	39	5.95%

Source: Accelitech Model
Moses Cone Health System

As previously stated, the capacity of SRS equipment is approximately 350 patients, or approximately half of the projected demand for SRS patient volume in Service Area 12. This capacity estimate is based on a model developed by Sg2 which employs the following assumptions: average treatment time of 140 minutes, three fractions of treatment per patient, operating 270 days per year, and10 hours per day. MCHS anticipates serving a significant portion of the projected Area 12 demand should it receive CON approval for an SRS capable linear accelerator, while a portion of the patients who live in the service area will receive treatment at other facilities that offer SRS technology. Of particular note, this projected Service Area 12 demand for SRS services matched with the capacity of SRS equipment underscores the vital need for SRS technology in this service area.

A service area population of 500,000 or more supports the need for SRS equipment that has a capacity of 350 patients annually. Table 3 presents a potential SRS patient volume scenario demonstrating that 295 patients in 2007 and 313 patients in 2012 could receive treatment at a CON approved MCHS facility. The projected 2012 patient volume is approximately 90% of capacity, thereby allowing for anticipated growth in the number of patients receiving treatment at such an SRS program.

Table 3

Service Area 12 SRS Patient Volume Scenario – 2007 and 2012

	2007	2012
Service Area 12 Population	547,202[1]	576,892[4]
Estimated SRS Patient Volumes	656[2]	695[2]
MCHS Market Share	45%[3]	45%[3]
MCHS SRS Patient Volumes	295	313
MCHS SRS Capacity Utilization[5]	84.3%	89.4%

[1] Proposed 2008 State Medical Facilities Plan, Page 113.
[2] See Table 2.
[3] Market share estimated based on current MCHS Medical Oncology market share percent.
[4] North Carolina Data Center.
[5] Based on annual capacity of 350 patients.

Source: As noted above.
Moses Cone Health System.

Alternatives Considered

Moses Cone Health System considered a number of alternatives to submitting this petition to adjust the need determination in the 2008 SMFP including maintaining the status quo, replacing an existing MCHS linear accelerator, and developing a relationship with another area radiation oncology provider. None of these options was deemed superior to submitting a petition for an adjusted need determination and, therefore, all were rejected.

Maintain the Status Quo

One alternative considered was to maintain the status quo and not pursue the acquisition of stereotactic radiosurgery (SRS) technology. This option would have the obvious advantage of eliminating the necessary capital cost. However,

this option would not allow patients in Service Area 12 to benefit from convenient access to SRS technology. Currently the closest provider of SRS treatment is located at NC Baptist Hospital in Winston-Salem, NC, which is approximately twenty-eight (28) miles from Greensboro, forty-three (43) miles from Reidsville, and almost fifty (50) miles from Eden, three of the major cities in Area 12. This distance may impede SRS referrals for many Area 12 residents. Exhibit III demonstrates excessive travel times and distances from established and CON pending SRS facilities. In addition, since SRS patients often have to return several times for treatment, a shorter travel distance will be more convenient for patients and their families.

The technology requested in this petition represents state-of-the-art technology. It can be used to treat intra and extracranial tumors, thus serving a large and expanding pool of potential patients. Moreover, SRS technology provides improved accuracy in targeting the tumor which greatly reduces damage to the surrounding, healthy tissue.

Replace an Existing MCHS Linear Accelerator

Replacement of an existing MCHS linear accelerator with SRS technology was also considered. Due to the high utilization levels of MCHS's four (4) existing linear accelerators, replacing an existing linear accelerator with SRS technology would significantly reduce capacity for serving radiation oncology patients. Table 4 lists the utilization of MCHS's existing linear accelerators.

Table 4

Moses Cone Health System Linear Accelerator Volumes FY 2002 – 2006

						Change FY 02-06	
	FY 2002	**FY 2003**	**FY 2004**	**FY 2005**	**FY 2006**	**#**	**%**
ESTVs	26,883	28,947	26,097	26,824	28,362	1,480	5.5%
# of Linear Accelerators	4	4	4	4	4	0	0.0%
ESTVs/Linear Accelerator	6,721	7,237	6,524	6,706	7,091	370	5.5%
% Utilization [1]	99.6%	107.2%	96.7%	99.3%	105.0%	5.5%	5.5%

Note: ESTV = Equivalent Single Treatment Visit

[1] Based on the annual capacity of 6,750 ESTV procedures, as set in the State Medical Facilities Plan.

Source: Annual Hospital License Renewal Applications

MCHS has been above 96% capacity since FY 2002 and for FY 2006 was operating at 105% of capacity.

As previously described, SRS patients are best served through equipment dedicated to providing SRS services. MCHS's historically high utilization of its existing linear accelerator capacity simply does not permit the replacement of one of these machines with a SRS capable linear accelerator. Under this scenario, both radiation oncology and SRS patients would suffer from unacceptable wait times for treatment.

Develop a Relationship with Another Area Radiation Oncology Provider

Moses Cone Health System also considered developing a relationship with another area radiation oncology provider. Table 5 lists close hospitals that provide radiation oncology services, the number of unduplicated patients treated, and the number of ESTV procedures performed in FY 2006.

Table 5

Selected North Carolina Hospitals Providing Radiation Oncology Services

	FY 2006	
Radiation Oncology Provider	**Number of Unduplicated Patients**	**Number of ESTV Procedures**
Moses Cone Health System	1,080	28,362
High Point Regional Health System	389 [1]	9,623[1]
Morehead Memorial Hospital	217	5,972
Alamance Regional Medical Center	305	7,991

[1] From 2006 Hospital License Renewal Application, p. 14 and 15 due to an apparent inconsistency in the 2007 Application as compared to other years, for the number of unduplicated patients.

Source: 2007 Hospital License Renewal Applications, p. 14 and 15.

Currently within Area 12, there are two other radiation oncology providers, High Point Regional Health System and Morehead Memorial Hospital. Neither of these programs have the scope and comprehensiveness of services necessary to develop a SRS program. Alamance Regional Medical Center, while outside Service Area 12 but located close to Moses Cone Health System, also lacks the capacity to serve additional SRS patients. The aforementioned hospitals are small to medium sized community hospitals and do not have the size, technological infrastructure, and breadth of physician specialties on staff to be a viable partner with MCHS to develop a SRS program. Supporting this conclusion, please see Exhibit IV for letters from High Point Regional Health System and Morehead Memorial Hospital supporting this petition.

The closest SRS provider to Area 12 is NC Baptist Hospital, located in Winston-Salem. UNC Hospital, the next closest facility that provides SRS treatments is fifty-six (56) miles from Greensboro, a distance which would cause referral and travel difficulties for patients in need of treatment.

After thoroughly examining these three alternatives, MCHS decided that submitting this petition was the best option to provide Area 12 residents with state-of-the-art technology within close proximity to their homes and without

reducing capacity for patients in need of highly utilized, traditional radiation treatments.

No Unnecessary Duplication of Health Care Resources

The addition of a need determination for a linear accelerator with SRS capability will not result in unnecessary duplication of health care resources for the following reasons:

1. Linear Accelerator Service Area 12 currently contains no SRS capable equipment. MCHS and its physicians are uniquely qualified to offer this service by expanding its well-established, well-utilized radiation oncology program.
2. MCHS's existing linear accelerators are operating above 100% capacity (6,750 ESTVs/linear accelerator) as noted in Table 4.
3. Patient volumes for SRS, both intra and extracranial, will grow substantially over the coming years due to the clinical applications of the technology and the expected growth in incidence of cancers that may benefit from treatment using SRS.
4. The current linear accelerator need methodology is service area based. Hence, it penalizes those providers who operate at high utilization while other service area providers do not. This situation limits a well-utilized program from upgrading existing equipment without incurring negative consequences for existing patients and clinical needs.

Adjusted Need Determination Request

Moses Cone Health System respectfully requests that the 2008 State Medical Facilities Plan include an adjusted need determination for a linear accelerator providing stereotactic radiosurgery capabilities in Service Area 12 based on the following criteria:

1. The Service Area 12 2007 resident population exceeds 500,000, a size sufficient to support a stereotactic radiosurgery program.

2. As documented in the Proposed 2008 State Medical Facilities Plan, Moses Cone Health System provided linear accelerator services above the performance threshold of 6,750 ESTVs per linear accelerator for FY 2006.
3. No stereotactic radiosurgery providers exist in Service Area 12. Moreover, the potential for establishing the need for a linear accelerator with SRS capability, absent an adjusted need determination, will not occur for many years to come.

EXHIBIT I

MOSES CONE [illegible]

Regional Cancer Center

501 North Elam Avenue
Greensboro NC 27403-1199

Writer's Direct Number

August 3, 2007

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Dear Ms. Brown:

I am pleased to support the petition for an adjusted need determination submitted by Moses Cone Health System (MCHS) requesting the addition of a linear accelerator with stereotactic radiosurgery (SRS) capabilities in service area 12 (Guilford and Rockingham Counties) to the 2008 State Medical Facilities Plan. As a practicing physician, I have first hand knowledge of how SRS could benefit my patients, and I firmly believe a variety of reasons justify the approval of Moses Cone's petition for Service Area 12.

Service area 12 has a large population and one linear accelerator provider, MCHS, which is operating above capacity. If MCHS were to replace an existing linear accelerator with SRS equipment, it would significantly reduce capacity, as throughput on SRS machines is much lower than on traditional linear accelerators. This would cause a significant barrier to access for patients in need of traditional radiation treatments as well as SRS, a new, cutting-edge technology. Therefore, we believe adding need for a linear accelerator with SRS technology is the only way to ensure high quality, accessible care to the residents of service area 12.

SRS is one of the fastest-growing areas of oncologic radiation therapy. As Radiation Oncologists, we are acutely aware of the increasing utilization of SRS therapies in treating a growing number of cancers. SRS provided via a linear accelerator now enables the delivery of high doses of radiation to intracranial tumors without a metal head frame and to extracranial tumors such as the spine, lung, prostate, liver, and pancreas, while maintaining and even improving submillimeter accuracy to target the tumor or lesion. Intercranial utilization of SRS is projected to increase based on several factors: the technology can be used for patients with multiple or recurrent brain lesions once thought to be untreatable; clinical efficacy will continue to improve for non-cancer indications, such as functional disorders and acoustic neuromas; treatment of brain metastases will increase due to improved survival rates for other primary cancers; and the increasing public awareness and interest in receiving state-of-the-art care.

We appreciate the opportunity to offer our support for this important petition, and we look forward to the Medical Facilities Planning Section's approval of the adjusted need determination for the addition of need for a linear accelerator with SRS capabilities in service area 12.

Sincerely,

Robert Murray, M.D.

MOSES CONE

Regional Cancer Center

501 North Elam Avenue
Greensboro NC 27403-1082

Writer's Direct Number

August 3, 2007

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
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We appreciate the opportunity to offer our support for this important petition, and we look forward to the Medical Facilities Planning Section's approval of the adjusted need determination for the addition of need for a linear accelerator with SRS capabilities in service area 12.

Sincerely,

James Kinard, M.D.

MOSES CONE

Regional Cancer Center

501 North Elam Avenue
Greensboro NC 27403-1199

Writer's Direct Number

August 3, 2007

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The Division of Health Service Regulation
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As Oncologists, we are acutely aware of the increasing utilization of SRS therapies in treating a growing number of cancers. We currently refer patients each year to SRS providers outside of area 12. We are acutely aware of the hardship this causes our patients who must make multiple trips to receive treatment.

We appreciate the opportunity to offer our support for this important petition, and we look forward to the Medical Facilities Planning Section's approval of the adjusted need determination for the addition of need for a linear accelerator with SRS capabilities in service area 12.

Sincerely,

John Feldmann, M.D.

MOSES CONE

Regional Cancer Center

501 North Elam Avenue
Greensboro NC 27403-1199

Writer's Direct Number

August 3, 2007

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Sincerely,

Peter Rubin, M.D.

MOSES CONE

Regional Cancer Center

501 North Elam Avenue
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Sincerely,

G. Bradley Sherrill, M.D.

Guilford Neurosurgical Associates, P.A.
1313 Carolina Street, Suite 300
Greensboro, NC 27401
Telephone (336) 272-4578
Fax (336) 272-5931

Ernesto M. Botero, M.D., F.A.C.S.*
Robert W. Nudelman, M.D., F.A.C.S.*
Henry J. Elsner, M.D., F.A.C.S.*
Mark W. Roy, M.D., Ph.D.*
Jeffrey D. Jenkins, M.D., F.A.C.S.*
Kyle L. Cabbell, M.D.*
Joseph D. Stern, M.D., F.A.C.S.*
James R. Hirsch, M.D.*

*Diplomates of the American Board of Neurological Surgery

August 3, 2007

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Raleigh, North Carolina 27699-2714

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I am pleased to support the petition for an adjusted need determination submitted by Moses Cone Health System (MCHS) requesting the addition of a linear accelerator with stereotactic radiosurgery (SRS) capabilities in service area 12 (Guilford and Rockingham Counties) to the 2008 State Medical Facilities Plan. As a practicing physician, I have first hand knowledge of how SRS could benefit my patients, and I firmly believe a variety of reasons justify the approval of Moses Cone's petition for Service Area 12.

Service area 12 has a large population and one linear accelerator provider, MCHS, which is operating above capacity. If MCHS were to replace an existing linear accelerator with SRS equipment, it would significantly reduce capacity, as throughput on SRS machines is much lower than on traditional linear accelerators. This would cause a significant barrier to access for patients in need of traditional radiation oncology as well as SRS, a new, cutting-edge technology. Therefore, we believe adding need for a linear accelerator with SRS technology is the only way to ensure high quality, accessible care to the residents of service area 12.

SRS is one of the fastest-growing areas of oncologic radiation therapy. As Neurosurgeons, we are acutely aware of the increasing utilization of SRS therapies in treating intracranial spinal tumors. SRS provided via a linear accelerator now enables the delivery of high doses of radiation to intracranial tumors without a metal head frame and to extracranial tumors such as the spine, lung, prostate, liver, and pancreas, while maintaining and even improving submillimeter accuracy to target the tumor or lesion. Intercranial utilization of SRS is projected to increase based on several factors: the technology can be used for patients with multiple or recurrent brain lesions once thought to be untreatable; clinical efficacy will continue to improve for non-cancer indications, such as functional disorders and acoustic neuromas; treatment of brain metastases will

increase due to improved survival rates for other primary cancers; and the increasing public awareness and interest in receiving state-of-the-art care.

We appreciate the opportunity to offer our support for this important petition, and we look forward to the Medical Facilities Planning Section's approval of the adjusted need determination for the addition of need for a linear accelerator with SRS capabilities in service area 12.

Sincerely,

Henry Elsner, MD

Robert Nudelman, MD

Mark Roy, MD

Jeffrey Jenkins, MD

Kyle Cabbell, MD

James Hirsch, MD

August 2, 2007

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

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cancers; and the increasing public awareness and interest in receiving state-of-the-art care.

We appreciate the opportunity to offer our support for this important petition, and we look forward to the Medical Facilities Planning Section's approval of the adjusted need determination for the addition of need for a linear accelerator with SRS capabilities in service area 12.

Sincerely,

Randy O. Kritzer, M. D.
Neurosurgeon
Carolina Neurosurgery, P.A.
301 E. Wendover Ave, Suite 211
Greensboro, NC 27401

August 2, 2007

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

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cancers; and the increasing public awareness and interest in receiving state-of-the-art care.

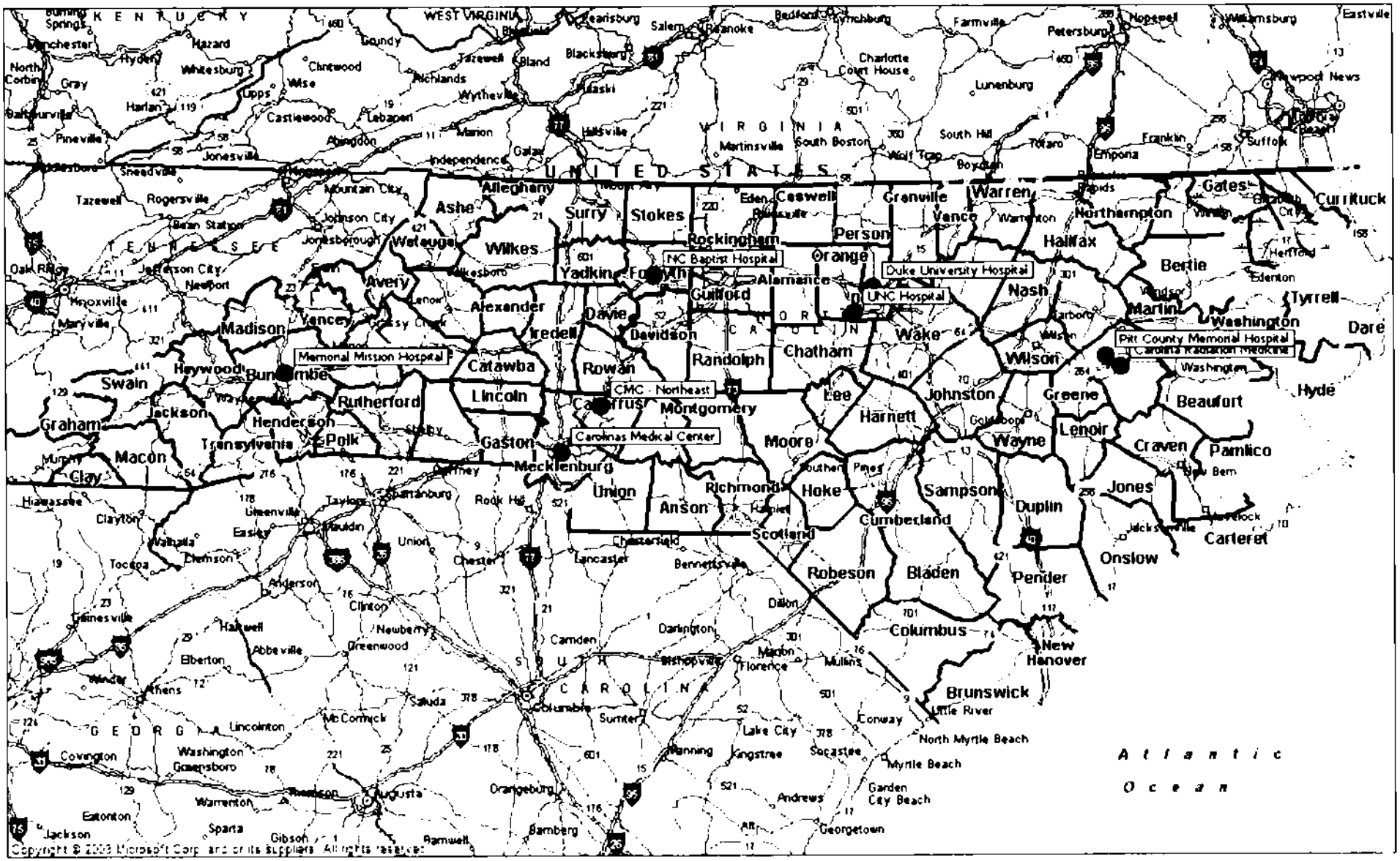
We appreciate the opportunity to offer our support for this important petition, and we look forward to the Medical Facilities Planning Section's approval of the adjusted need determination for the addition of need for a linear accelerator with SRS capabilities in service area 12.

Sincerely,

David Jones, M. D.
Neurosurgeon
Carolina Neurosurgery, P.A.
301 E. Wendover Ave, Suite 211
Greensboro, NC 27401

EXHIBIT II

Exhibit II
Existing SRS Locations in North Carolina



Linear Accelerator Service Area 12

EXHIBIT III

Exhibit III
Distance and Travel Times to Existing SRS Facilities

	Area 12 Major Cities			
	Greensboro (Guilford Co.)	**High Point (Guilford Co.)**	**Reidsville (Rockingham Co.)**	**Eden (Rockingham Co.)**
Carolinas Med Center, Charlotte	94.5 miles 1 hour, 41 minutes	84.2 miles 1 hour, 27 minutes	118.5 miles 2 hours, 6 minutes	131.0 miles 2 hours, 24 minutes
CMC - Northeast, Concord	69.7 miles 1 hour, 15 minutes	59.3 miles 1 hour	93.6 miles 1 hour, 40 minutes	106.1 miles 1 hour, 58 minutes
Carolina Radiation Medicine, Greenville	162.3 miles 2 hours, 53 minutes	176.2 miles 3 hours, 3 minutes	182.6 miles 3 hours, 15 minutes	202.2 miles 3 hours, 48 minutes
Duke University Hospital, Durham	52.1 miles 58 minutes	65.9 miles 1 hour, 9 minutes	64.8 miles 1 hour, 19 minutes	77.3 miles 1 hour, 38 minutes
Memorial Mission Hospital, Asheville	169.8 miles 2 hours, 47 minutes	161.4 miles 2 hours, 39 minutes	194.3 miles 3 hours, 16 minutes	192.1 miles 3 hours, 27 minutes
NC Baptist Hospital, Winston-Salem	27.9 miles 35 minutes	22.0 miles 29 minutes	43.3 miles 55 minutes	47.9 miles 1 hour, 11 minutes
Pitt County/Brody School, Greenville	161.0 miles 2 hours, 51 minutes	174.8 miles 3 hours, 2 minutes	181.2 miles 3 hours, 13 minutes	200.9 miles 3 hours, 46 minutes
UNC Chapel Hill, Chapel Hill	56.0 miles 1 hour, 3 minutes	69.9 miles 1 hour, 14 minutes	68.8 miles 1 hour, 24 minutes	81.2 miles 1 hour, 42 minutes

Source: Microsoft MapPoint 2004

EXHIBIT IV

High Point Regional Health System

Jeffrey S. Miller
President

August 2, 2007

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Ms. Brown:

I understand that Moses Cone Health System is submitting a petition requesting an adjusted need determination for the 2008 State Medical Facilities Plan to add a linear accelerator with stereotactic radiosurgery capabilities to Service Area 12.
High Point Regional Health System is one of the three established providers of radiation oncology services in Linear Accelerator Service Area 12. I believe the residents of Guilford and Rockingham counties could greatly benefit by gaining greater access to stereotactic radiosurgery services. Moreover, it appears that petitioning for an adjusted need determination is the most effective approach for establishing the need for this valuable technology. I urge the State Health Coordinating Council to approve the petition submitted by Moses Cone Health System.

Sincerely,

Jeffrey S. Miller
President

601 N. Elm Street • P.O. Box HP-5
High Point, North Carolina 27261
Telephone (336) 878-6960
Fax (336) 878-6158

MOREHEAD
MEMORIAL·HOSPITAL

August 3, 2007

Ms. Elizabeth Brown, Chief
Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

Dear Ms. Brown,

I understand that Moses Cone Health System is submitting a petition requesting an adjusted need determination for the 2008 State Medical Facilities Plan to add a linear accelerator with stereotatic radiosurgery capabilities to Service Area 12. Morehead Memorial Hospital is one of the three established providers of radiation oncology services in Linear Accelerator Service Area 12. This new linear accelerator will not take volume from any of the existing facilities as it will be a dedicated unit only used for stereotatic radiosurgery, a service currently not available in Service Area 12. I believe the residents of Guilford and Rockingham counties could greatly benefit by gaining greater access to stereotatic radiosurgery services. Moreover, it appears that petitioning for an adjusted need determination is the most effective approach for establishing the need for this valuable technology. I urge the State Health Coordinating Council to approve the petition submitted by Moses Cone Health System.

Sincerely,

Robert A. Enders, Jr.
President

117 East Kings Highway
Eden, North Carolina 27288-5201
TEL 336.623.9711
www.morehead.org

Radiation Oncology Services -

Technology and Equipment
Committee Meeting

August 29, 2007

Radiation Oncology Services - Linear Accelerators

<u>Comments</u> Related To

Linac Petition-1: Moses Cone Health System

Comment -1 Jim Whiting
Comment -2 Dr. Henry A. Pool

Greensboro PH
7-20-07
LinAC
Tom

Proposed 2008 State Medical Facilities Plan

Public Hearing

July 20, 2007

Moses Cone Health System

Remarks Made Supporting an Adjusted

Need Determination for a Linear Accelerator

with Stereotactic Radiosurgery Capability

in Service Area 12

Good Afternoon. My name is Jim Whiting, and I am the Vice President for Moses Cone Health System's Regional Cancer Center. My remarks today address the need to provide immediate access to Stereotactic Radiosurgery (SRS) technology for the residents of linear accelerator Service Area 12 comprising Guilford and Rockingham counties. Serving this unmet need is essential to insuring a full array of state-of-the-art therapy services to this region's population, which currently totals over 541,000 residents. However, existing State Medical Facilities Plan need methodologies effectively block the addition of SRS technology in our area. As a result, Moses Cone Health System intends to submit a petition for an adjusted need determination for the addition of a linear accelerator with SRS capabilities.

Our petition will be based on the following major points:

1. Stereotactic radiosurgery is both a proven and expanding modality for the treatment of both intra and extra cranial tumors.

2. Physicians directly involved with the care of patients who could benefit most from SRS, most notably neurosurgeons, thoracic surgeons and radiation oncologists on staff at Moses Cone Health System, strongly support the addition of this technology.

3. Current geographic access to SRS services for Area 12 residents is limited.

- No SRS providers exist in Guilford or Rockingham counties.

- While other service areas provide SRS, travel to these programs imposes a burden on Area 12 patients and families.

4. The Service Area 12 resident population is of a sufficient size, greater than 500,000, to warrant the development of a SRS program.

5. The current SMFP need methodology for linear accelerators is area and not provider specific. As a result, lower utilized facilities in a given service area can prevent the determination of an identified need despite one or more providers operating at or above capacity.

   This situation is currently found in Area 12, where MCHS operates at over 100% capacity on its four (4) linear accelerators, while Morehead Memorial Hospital and High Point Regional Health System operate at 79.9% and 69.2%, respectively.

6. MCHS has considered a number of alternatives to requesting an adjusted need determination:

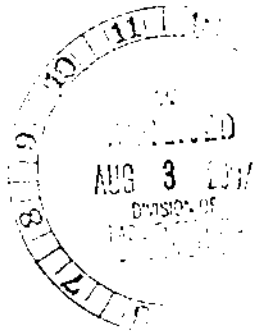
   - The status quo fails to meet the unmet need for SRS services.

   - Replacing an existing linear accelerator at MCHS with a stereotactic radiosurgery machine significantly reduces MCHS radiation oncology capacity. SRS patients require longer treatment times; a machine dedicated to SRS will best meet the clinical needs of these patients.

7. No unnecessary duplication of services will result from the approval of this adjusted need determination. Indeed, our petition is based on the current lack of SRS capabilities in Area 12.

Our petition will expand on each of these major points. I am hopeful that the Medical Facilities Planning Section staff and the State Health Coordinating Council will look favorably at our request.

Thank you.



August 3, 2007

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Medical Facilities Planning Section
The Division of Health Service Regulation
North Carolina Department of Health and Human Services
2714 Mail Service Center
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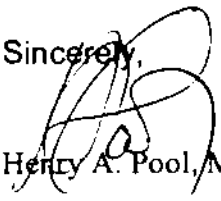
Sincerely,



Henry A. Pool, M.D.

Technology and Equipment Committee Meeting

August 29, 2007

Radiation Oncology Services - Linear Accelerators

Material Related To

Linac Petition-2: Cape Fear Valley Health System

PETITION FOR A SPECIAL NEED DETERMINATION FOR A CYBERKNIFE STEREOTACTIC RADIOSURGERY SYSTEM IN THE PROPOSED 2008 STATE MEDICAL FACILITIES PLAN FOR LINEAR ACCELERATOR AREA 18

PETITIONER

Lynda B. Clark, Vice President for Professional Services
Cape Fear Valley Health System
1638 Owen Drive
Fayetteville North Carolina 28302-2000
910/609-6549

STATEMENT OF THE REQUESTED ADJUSTMENT

Cape Fear Valley Health System ("Cape Fear Valley") submits this petition for an adjustment in the Proposed 2008 State Medical Facilities Plan ("SMFP") to recognize a special need determination for a CyberKnife Stereotactic Radiosurgery System in linear accelerator area 18 ("Area 18")[1].

We concur with the preliminary determination from the Technology and Equipment Committee noted on May 24, 2007 that based on the SMFP need determination methodology there is no need for an additional linear accelerator in the state. We also agree with the Technology Committee that no additional GammaKnife is needed in the state.

Based on information provided on the following pages, Cape Fear Valley respectfully requests that consideration be given to a special need determination in Area 18 for the development of a CyberKnife Stereotactic Radiosurgery System based on the unique needs of the area.

REASONS FOR THE PROPOSED ADJUSTMENT

History of Stereotactic Radiosurgery

Stereotactic Radiosurgery (SRS) is a highly precise form of radiation therapy delivered in a single high-dose session with effects so dramatic it is considered surgical in nature. Stereotactic Radiotherapy (SRT) is similar in effect but fractionated, meaning 2-5 treatments instead of just one treatment. SRS and SRT have been used historically to treat certain types of malignant and non-malignant brain tumors, brain malformations, inoperable brain tumors, as well as recurrent brain tumors. Until recently, almost all SRS and SRT was limited to intracranial (brain and upper spine) lesions using head frames bolted to a patient's skull as well as the treatment table to immobilize the patient for treatment. SRS and SRT

[1] Area 18 in the SMFP includes Cumberland, Bladen, Robeson and Sampson counties.

treatments for intracranial lesions have traditionally been performed using linear accelerators modified to deliver these precise treatments, proton therapy units found only in a few locations in the world, and Cobalt-60 dedicated units known as a GammaKnife.[2]

Stereotactic Radiosurgery (SRS) has been around for many years, though mainly in university settings. SRS/SRT programs have historically been provided by academic medical centers due to the enormous financial and physical resources required for the lengthy procedures and research. At the opposite end of the linear accelerator spectrum, community hospital settings have neither the financial nor physical resource backing for research, especially the excess capacity needed on their linear accelerators to perform SRS/SRT. Thus, SRS/SRT programs have mainly been limited to the university setting. As an example, typical SRS patient treatments take multiple hours to perform: first, attaching the headframe to the skull or preparing immobilization devices; second, imaging the treatment area; third, performing the computerized treatment plan; and finally, treating the patient. All of these processes take place with the patient lying on an uncomfortable treatment table and over multiple hours. Staff must be present throughout most of the procedures including radiation oncologists, physicists, dosimetrists, nurses, radiation therapists, and other support staff. During this long process, the linear accelerator cannot be used for external beam radiation therapy ("EBRT") treatments, tying up valuable resources for an extended period of time.

In the early 2000's, a revolutionary SRS/SRT unit was developed called CyberKnife and with it SRS/SRT services began expanding beyond the academic medical center setting. CyberKnife contains a small linear accelerator mounted on a robotic arm that delivers high doses of radiation anywhere in the body without invasive headframes bolted to skulls or other invasive immobilization. This astounding technology accomplishes this mission that no other SRS/SRT product has done (intra and extracranial treatments with little or no immobilization) by visually tracking the tumor during treatment and moving with the tumor for the entirety of the treatment. CyberKnife is an SRS/SRT dedicated unit used solely to treat intracranial and extracranial lesions anywhere in the body, and like the GammaKnife, is not capable of performing typical EBRT, the most common procedures performed with linear accelerators. CyberKnife represents a phenomenal breakthrough for SRS and SRT, for which there is no comparison.

In contrast to traditional SRS/SRT technology, CyberKnife requires no invasive immobilization procedures to be performed, imaging and treatment planning are done on the virtual patient prior to the day of treatment and patient treatments generally take only 30-90 minutes depending on the tumor volume treated and the tumor location. Because of this, CyberKnife procedures in established centers range from 4-7 patient treatments a day. Intracranial tumors are typically treated and completed in just one treatment with CyberKnife. Extracranial tumors

[2] Currently, Wake Forest University Baptist Medical Center and Pitt County Memorial Hospital operate GammaKnife equipment. The following providers have SRS/SRT modified linear accelerators: Carolinas Medical Center (1), Duke (2), Memorial Mission (1), Pitt County Memorial Hospital (2), UNC (1), Wake Forest (1), Carolina Radiation Medicine (1).

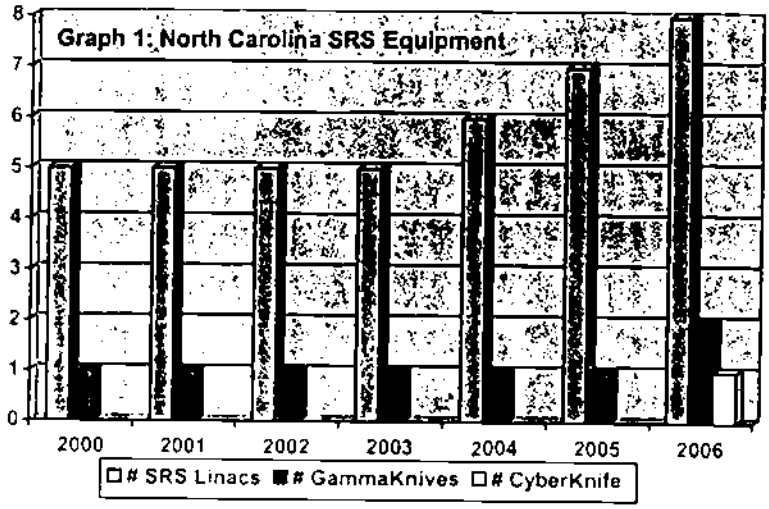
generally range from 3-5 treatments with CyberKnife to complete their treatment course. The resource allocation for CyberKnife still requires the same staff members to participate in the SRS/SRT process; however, less time commitment per patient and greater flexibility with planning yields, greater efficiency and the ability to treat more patients daily as compared to traditional linac-based SRS/SRT.

CyberKnife can easily treat 350 new SRS/SRT patients annually, as evidenced by successful programs throughout the United States, many of which are in community hospital settings and installing second CyberKnife units. The compelling and undisputable evidence nationwide shows that traditional linac-based SRS/SRT programs simply are not widely adopted nor widely used due to the multitude of inefficiencies noted earlier, even on dedicated SRS/SRT units. Clearly, CyberKnife affords the greatest SRS/SRT utilization and efficiency in the market today. Even more compelling than the efficiencies gained is that CyberKnife is designed for a different population of patients than those receiving traditional EBRT, a population largely receiving less optimal treatment or no treatment at all.

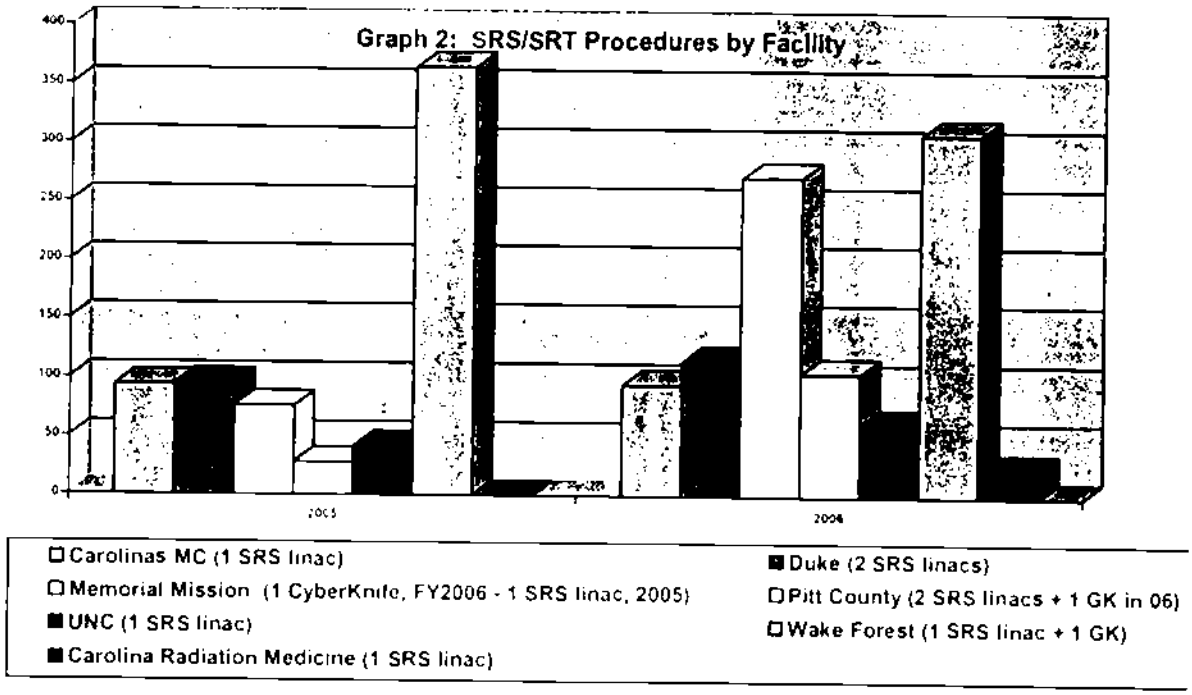
Currently CyberKnife services are provided at Memorial Mission Hospitals (Asheville) and Northeast Medical Center (Concord). UNC Hospitals (Chapel Hill) has been approved for the service and East Carolina University (Greenville) has applied for approval.

Recent NC Experience with Stereotactic Radiosurgery

According to the 2007 SMFP, there were eight operational SRS/SRT units in 2005 that performed a total of 700 SRS/SRT procedures on seven linac-based SRS units and one GammaKnife unit. According to the draft 2008 SMFP, there were 982 SRS/SRT procedures performed on eleven operational SRS/SRT units in 2006, including eight linac-based units, one CyberKnife, and two GammaKnife units. Graph 1 below distinguishes the number and type of SRS/SRT equipment installed and functional in North Carolina from 2000-2006.



The chart below shows the number of SRS/SRT procedures at each of the facilities operating SRS/SRT equipment. The clear leaders in SRS/SRT treatments performed in North Carolina are Wake Forest using GammaKnife for the majority of their SRS/SRT procedures and Memorial Mission using CyberKnife for 100 percent of their SRS/SRT. None of the linac-based providers performed substantial SRS/SRT procedures compared to the dedicated SRS/SRT GammaKnife and CyberKnife units.



The graph and table below show the growth in SRS/SRT over the past seven years and the low number of procedures performed on Linac SRS units as compared to dedicated SRS/SRT units (GammaKnife and CyberKnife). In one year a single CyberKnife unit performed almost as many SRS/SRT procedures as eight Linac SRS units.

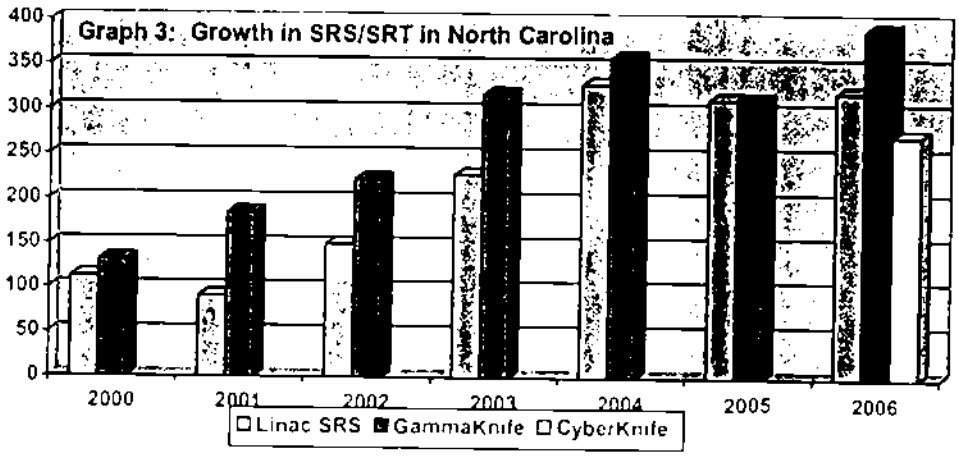


Table 1 – SRS Utilization by Type SRS Equipment

Data Year	SRS In-Use Linacs	Linac SRS Proc	Avg SRS Per Linac	Cyber #	Cyber SRS Proc	Avg SRS Per Cyber	Gamma #	SRS Gamma Proc	Avg SRS Per Gamma	State Linac Volumes
2000	5	113	23				1	132	132	512,578
2001	5	91	18				1	185	185	558,311
2002	5	150	30				1	223	223	553,506
2003	5	228	46				1	318	318	556,321
2004	6	329	55				1	358	358	556,224
2005	7	388	55				1	312	312	577,262
2006	8	320	40	1	272	272	2	390	195	573,184
Seven Years Cumulative		1,619			272			1,918		3,887,386

For the reporting year 2007, three CyberKnife units will be operational in North Carolina with projected volumes greater than 500 procedures, exceeding volumes performed on either GammaKnife or Linac SRS units in 2006. CyberKnife is expected to experience such growth because it is the only system uniquely able to combine continuous image guidance, automatic correction with computer controlled robotics, minimal (if any) immobilization requirements, and ability to deliver ablative radiosurgery with sub-millimeter accuracy anywhere in the body with minimal to no side effects.

The only site in North Carolina to date with CyberKnife experience is Memorial Mission, which experienced no reduction in EBRT volumes when a CyberKnife was added, as shown in Table 2 below.

Table 2 – Equivalent Simple Treatment Visits ("ESTVs") 2007 and Proposed 2008 SMFP

Memorial Mission ESTVs	FY2005	FY2006	Increase in FY2006
Excluding CyberKnife ESTVs	19,569	19,949	380
Including CyberKnife ESTVs	19,569	20,766	1,197

Linear Accelerator Need Determination in Area 18

Currently, 112 linear accelerators are in operation or are planned for development in North Carolina. Five linear accelerators operate in Area 18, three at Cape Fear Valley Medical Center (Cape Fear Valley's main campus in Fayetteville), one at Health Pavilion North (Cape Fear Valley's north Cumberland County outpatient facility) and one at Southeastern Regional Medical Center in Lumberton, North Carolina. The need methodology in the SMFP requires meeting two of three of the following criteria before a need is established:

1) Population per accelerator is 120,000 or more;
2) More than 45% of the patients served by the Area's linear accelerators are residents from outside the Area;

3) Equivalent Simple Treatment Visits ("ESTVs") divided by 6.750 (linear accelerator capacity as defined by the SMFP) less the number of existing accelerators in the Area is greater than or equal to .25.

Area 18 meets Criteria 3 and actually shows a +.50 need determination in the proposed 2008 SMFP, but does not meet Criteria 1 or 2 (Area 18 population per accelerator = 107,401; 12% of patients reside outside Area 18). Therefore, no need is established in Area 18 for an additional linear accelerator.[3] Also, the 2006 and 2007 SMFP determined no need for an additional linear accelerator in Area 18.

In November 2006, Cape Fear Valley submitted an application for the acquisition of CyberKnife equipment to provide SRS/SRT services. The application was denied by the CON Section based on its interpretation that a CyberKnife is subject to the regular need methodology. It should be noted that GammaKnife equipment, which is used only for SRS intracranial treatments, is not subject to this linear accelerator need methodology. Likewise, CyberKnife can only be used for SRS/SRT intracranial and extracranial treatments and cannot perform EBRT treatments. As described more fully below, there is a critical need for SRS/SRT services in Southeastern North Carolina where currently no providers offer this service. Given the need for the service and the clinical expertise, resources and capabilities present at Cape Fear Valley to support the service, a special need should be determined for a dedicated SRS/SRT program in Area 18.

Special Needs of Area 18

A number of North Carolina communities will gain access to CyberKnife technology by replacing existing linear accelerators. UNC Hospitals is replacing an existing low-utilization linear accelerator with a CyberKnife unit and East Carolina University proposes to do the same. Under these circumstances, need in the SMFP is not required because existing equipment is being replaced, though clearly these units are dissimilar. Such a replacement would be similar to replacing an outdated cobalt unit with a GammaKnife.

Replacing an existing linear accelerator in Area 18 is not an option available to providers because existing demand for Area 18 linear accelerators already exceeds the capacity threshold in the SMFP methodology. Of the 27 SMFP linear accelerator areas, only one other, area 17[4], exceeds the capacity threshold by more than .25 as required in the linear accelerator need methodology. As noted previously, CyberKnife is a dedicated unit that is capable of performing only SRS/SRT. SRS/SRT is a critical need in southeastern North Carolina and represents a new treatment choice for a largely new population of patients in this region. Replacing a currently fully utilized linear accelerator in order to gain a CyberKnife would limit EBRT treatment capacity and is certainly not in the best interest of the patients we serve.

---

[3] The SMFP also does not establish a linear accelerator need in any other Area.

[4] Area 17 has a population of approximately 295,400 residents and includes Moore, Hoke, Lee, Montgomery, Scotland and Richmond counties

Recent experience in Area 18 indicates that as linear accelerators are added capacity is quickly absorbed. When Cape Fear's fourth linear accelerator became operational at Health Pavilion North in Fayetteville in fiscal year 2006, the unit was operating at full capacity within five months. According to the SMFP linear accelerator need determination methodology, a fully utilized linear accelerator performs 6,750 ESTVs annually. For the 2006 reporting period, Cape Fear Valley actually performed 27,631 ESTVs on 4 linear accelerators, or 6,908 ESTVs per unit, even with the fourth linear accelerator operational for only five months of the reporting year. For Area 18, 37,115 ESTVs were performed in 2006 on five accelerators or 7,423 ESTVs per unit owned by Cape Fear Valley or through contracted services with Southeastern Regional Medical Center. Growth of EBRT, the most common radiation treatments, is only expected to continue, meaning that Cape Fear Valley will likely need to add more traditional linear accelerators if there is future need determined in the SMFP.

Moreover, Area 18 has a large population of over 537,000 people, which is more than adequate to support a dedicated SRS/SRT service. No other linear accelerator service area in the State has a large enough population to support a dedicated SRS/SRT service coupled with the lack of capacity in existing linear accelerator units, precluding the ability to replace an existing EBRT linear accelerator with a CyberKnife. In the letter under Attachment 1, Dr. Hugh Bryan, Medical Director of Cape Fear Valley's Radiation Oncology department describes SRS, the need for the service in Area 18 and how SRS patients are different from other radiation therapy candidates.

Also, attached are letters from other radiation oncologists in the country addressing the differences between external beam therapy and SRS. Attachment 2 includes a letter from Dr. Mark J. Brenner, Chief of Radiation Oncology at Sinai Hospital in Baltimore. Sinai has treated over 1,000 patients with CyberKnife technology and recently started utilizing its second unit. Attachment 3 includes a letter from Dr. Clinton A. Medbery, President of Southwest Radiation Oncology in Oklahoma City, also noting that that CyberKnife SRS is not a replacement for standard linear accelerator treatments.

Projected Demand for CyberKnife in Area 18

As noted in Table 3 below, Cape Fear Valley projects that an Area 18 CyberKnife will annually serve approximately 250 patients and provide approximately 620 CyberKnife treatments by the third year of operation in addition to more than 19,000 projected EBRT linear accelerator treatments. This is a conservative estimate based on Cape Fear Valley 2006 radiation therapy patients with specific types of inoperable cancer or who have incurred maximum radiation treatments for their lesions (see Table 4 below). This extraordinary need cannot be met with traditional linear accelerator equipment, but requires stereotactic radiosurgery technology. This request for a CyberKnife stereotactic radiosurgery system in Area 18 is required to meet the critical needs of well over 500,000 residents in our four-county service area.

Table 3 -- Cape Fear Valley Projections						
Data Year	Linacs	Linac Patients	Linac Treatments (not ESTVs)	Cyber-Knives	CyberKnife Patients	CyberKnife Treatments
2006 Actual	4[1]	893	17,388			
2007 Projected	4	911	17,736			
2008 P	4	929	18,091			
2009 P	4	948	18,452	1	150	375
2010 P	4	967	18,821	1	200	500
2011 P	4	986	19,198	1	250	620

(1) Fourth Linear accelerator became operational in May 2006

Table 4 Cape Fear Valley CyberKnife Candidates In 2006			
AREA TREATED	# OF PATIENTS TREATED WITH EXTERNAL BEAM RADIATION AT CAPE FEAR VALLEY	% TREATABLE WITH CYBERKNIFE	TOTAL CYBERKNIFE CANDIDATES
Primary malignant Head and Neck tumors	48 patients	40%	19
Primary malignant Brain tumors	29 patients	30%	9
Primary lung tumors	90 patients	30%	27
Metastatic lung tumors	39 patients	25%	10
Pancreatic tumors	10 patients	75%	8
Renal tumors	5 patients	30%	2
Prostate cancer	139 patients	50%	70
Total	426 patients		178

Over 200 peer reviewed papers and book chapters have been published from 1991 through 2007 regarding CyberKnife SRS and its efficacy for the treatment areas noted above. Cape Fear Valley will provide a clinical dossier of the publications to the Planning Section upon request.

ADVERSE EFFECTS ON THE POPULATION OF THE AFFECTED AREA THAT ARE LIKELY TO ENSUE IF THE ADJUSTMENT IS NOT MADE

Cape Fear Valley conservatively identified 178 distinct patients for SRS treatments based on its current population base and projects that at least 250 patients will need SRS by 2011. Area 18 providers cannot replace an existing linear accelerator with a CyberKnife unit, because all existing units are already fully utilized performing EBRT. Therefore, these patients will lack access to CyberKnife technology unless they receive services from one of the three currently approved CyberKnife providers. The closest of these providers is Chapel Hill, which is two hours or more away from much of Area 18. Given the high demand anticipated by the new service at UNC there is no assurance that Area 18 residents will have access to this equipment even if they are able to drive to Chapel Hill. Patients in southeastern North Carolina do not have practical or convenient access to SRS/SRT. Without this critical choice,

patients may choose less optimal treatments (if there are choices), receive no treatment at all, or die.

A STATEMENT OF ALTERNATIVES TO THE PROPOSED ADJUSTMENT THAT WERE CONSIDERED AND FOUND NOT FEASIBLE

Cape Fear Valley has explored maintaining the status quo, which means that Area 18 will not have access to a SRS/SRT program. In fact, currently a SRS/SRT program is not available anywhere in Southeastern North Carolina (HSA V). Maintaining the status quo is not an option given the need as described above.

The second alternative we explored is replacing an existing linear accelerator with a CyberKnife dedicated to SRS/SRT. As described above, SRS/SRT is not an alternative for patients who receive external beam treatments. Rather, SRS/SRT represents a population of patients that generally have inoperable tumors, are not surgical candidates, have received maximum external beam treatments to an area, or choose SRS/SRT rather than surgery. Therefore, replacing an existing linear accelerator with a CyberKnife is only a valid option when the accelerator is not being fully utilized. Since this is not the case in Area 18, replacement is not an option.

EVIDENCE THAT HEALTH SERVICE DEVELOPMENT PERMITTED BY THE PROPOSED ADJUSTMENT WOULD NOT RESULT IN UNNECESSARY DUPLICATION OF HEALTH RESOURCES IN THE AREA.

Other CyberKnife approved or operating units are located in Asheville NC (six hours distance from Fayetteville), Concord, NC (three hours distance) and Chapel Hill (two hours distance). In fact, there are no SRS services or equipment in southeastern North Carolina. CyberKnife units are unique to other SRS/SRT technologies because it is the only system that can clinically ablate tumors anywhere in the body, without immobilization, and with sub-milliliter accuracy. Almost all other forms of SRS/SRT are mainly limited to intracranial SRS/SRT treatments. CyberKnife represents a phenomenal breakthrough in SRS/SRT technology that will undoubtedly raise the bar in SRS/SRT treatment delivery.

PETITIONERS SHOULD ASSUME THE SAME SERVICE AREA DEFINITIONS AS GIVEN IN THE PROGRAM CHAPTERS OF THE PROPOSED SMFP.

Area 18 was assumed for service area purposes for this petition.

OTHER RECOMMENDATIONS

Stereotactic Radiosurgery and Stereotactic Radiotherapy are unique and separate from external beam radiation therapy. As such, these procedures and the dedicated equipment used to deliver these treatments should be consistently reported and accounted for accurately in the inventory: (1) the "GammaKnife" heading would be more accurately changed to "Stereotactic Radiosurgery and Stereotactic Radiotherapy". The current methodology of reporting all types of SRS/SRT under the GammaKnife heading is inaccurate and misleading; (2), the Facility Inventory-Service Volume heading should contain the type of SRS/SRT equipment, either dedicated SRS/SRT unit or multi-functional linac used and the SRS/SRT procedure count produced from that equipment; and (3), need determination methodologies for SRS/SRT dedicated units like GammaKnife and CyberKnife, need to be developed that include specific criteria based on population, utilization, and location to provide the best patient access for these services throughout the state.

LETTERS OF SUPPORT

Attached are letters received to date supporting the need for an adjustment to the State Medical Facilities Plan to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18.

SOUTHEASTERN RADIATION ONCOLOGY

5 July 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Facilities Services
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Special need determination for CyberKnife, Cape Fear Valley Health System

Dear Mr. Elkins:

For the past 25 years, the Cancer Center at Cape Fear Valley has been caring for the people of southeastern North Carolina. Our commitment has been providing optimal state of the art treatment at Home and having the capacity to take care of every one who needs our services. We believe we offer the most comprehensive program in our region. We now have four fully utilized linear accelerators, three at Cape Fear Valley Health System and one at our recently opened facility in northern Cumberland County, Health Pavilion North. We also have a contract to manage the Radiation Oncology Division of Gibson Cancer Center of Southeastern Regional Medical Center in Lumberton. Therefore, we are directly involved in the care of patients from a large part of southeastern North Carolina from the Research Triangle down to Wilmington.

Our patients' access to the latest and best technology has rivaled that of our neighboring university hospitals. We now offer three dimensional conformal radiation therapy, intensity modulated radiation therapy and image guided radiation therapy. We have an extensive brachytherapy program that includes prostate implants and high dose rate therapy for gynecologic malignancies and partial breast irradiation, i.e. MammoSite.

Access to the latest technology is important but we also offer services that address the mind, body and soul of our patients both during and after treatment. Our Oasis Complementary Medicine Program includes six different support groups for patients and their families, nutritional classes, Healing Touch, Tai Chi, Reflexology, Massage Therapy and Look Good Feel Better.

While we are constantly refining and updating our existing programs we also have an on going obligation to evaluate new treatments that should be available to our patients and that will be future benchmarks for a comprehensive community cancer center. We therefore previously submitted a proposal to obtain a Certificate of Need to develop a stereotactic radiosurgery program based on the CyberKnife Radiosurgery system. Before doing so we carefully analyzed the needs of the patients we serve, our ability to meet

J. Hugh Bryan, M.D.
P.O. Box 41208 · Fayetteville, NC 28309 · 910 609-6693 · 800 682-3567 · FAX 910 609-6315
Cape Fear Valley Medical Center

those needs and the potential impact of this service on our existing program as well as the other programs in our area. We conferred with two representatives of the CON Division Facility Services regarding our intent prior to filing our application and we were led to believe that our application was appropriate. We feel that our subsequent proposal fully satisfied the rules and guidelines that we were led to believe existed at that time for major medical equipment. Furthermore, we believe that our application was denied based on the faulty assumption that a CyberKnife is a traditional linear accelerator. This would be tantamount to categorizing a GammaKnife as a cobalt machine.

Stereotactic radiosurgery depends upon exquisite high resolution imaging of the target (lesion/tumor) and the surrounding normal structures and the ability to deliver a very high dose of radiation to that target with sub-millimeter accuracy using a large number of small cross-fired radiation beams as a non-invasive surgical knife. This use of radiation is aptly termed "surgery without a knife".

Patients who are candidates for radiosurgery are a unique group and most often simply have no other alternative. They are often medically inoperable due to pre-existing conditions such as chronic lung disease, coronary artery disease, etc. The tumor may be surgically unresectable. They may have recurrent tumor within a previously irradiated area.

In other words, these are patients that you otherwise just could not treat in any other way. Treating them, therefore, does not decrease the workload on your existing linear accelerators. As a matter of fact, statistics from departments with a CyberKnife show an increase in the number of patients receiving traditional radiation therapy. This phenomenon is generally attributed to an enhanced departmental image which leads to an increased number of referrals.

The GammaKnife was the first instrument developed for radiosurgery. This machine focuses 201 beams of gamma radiation from 201 separate cobalt sources on a precise target. It is limited to neurosurgical/brain-only applications and requires immobilization with a rigid head frame that is attached to the skull with four pins. Treatment planning may require several hours thereafter and the head frame must remain in place. Therefore, due to the complexity of the set-up and patient tolerance, GammaKnife treatment is limited to a single fraction.

The foundation of radiation oncology departments is the traditional linear accelerator. Recent advances in linear accelerator technology include intensity modulated radiation therapy (IMRT) and image guided radiation therapy (IGRT). These techniques allow for more precise irradiation of the intended target while limiting the dose to adjacent critical structures. Several machines, e.g., Varian's Trilogy, Elekta's Synergy and BrainLab's Novalis, are designed to be "all purpose" units capable of standard treatment as well as intracranial and extracranial stereotactic radiosurgery. However, recent surveys including an analysis of these machines in our own State shows that they are underutilized for this purpose.

We considered these all-purpose linear accelerators as well as Tomotherapy when we made our choice and after considerable consultation and thoughtful analysis we are absolutely convinced that none of them performs intracranial and extracranial stereotactic radiosurgery with the precision, elegance and efficiency of CyberKnife.

The CyberKnife was developed exclusively for stereotactic radiosurgery. The CyberKnife includes a light, compact 6MeV linear accelerator mounted on a precise computer driven robotic arm. Patients are treated lying on a couch while the robotic arm moves the small linear accelerator around then. The machine is capable of delivering beams as small as 5 mm from 1600 different positions. It can therefore deliver a homogenous dose to a target of any shape with sub-millimeter accuracy by superimposing a very large number of suitably angled and weighted small beams. Uniquely, the position of the target is continuously monitored throughout treatment and the robot trajectory is appropriately adjusted to account for any patient movement. CyberKnife can therefore treat lesions that move with respiration. The patients can be treated without uncomfortable body or head frames and treatment can be fractionated, i.e., one to five treatments instead of only one, and this may be beneficial when the target closely approximates a critical radiosensitive structure.

The CyberKnife can be used to treat a wide variety of medical conditions including cancers, benign tumors, and lesions anywhere in the body and now at least 50% of treatments are extracranial. CyberKnife radiosurgery can be used for benign intracranial lesions such as acoustic neuroma, meningioma, pituitary adenoma, arteriovenous malformation and trigeminal neuralgia. It often provides superior palliation in patients with brain metastases. Patients with early stage cancers of the lung or prostate can achieve results comparable to surgery if they wish to avoid an operation or if they are medically unfit for an invasive procedure. Unprecedented local control can be achieved in certain inoperable tumors, e.g. pancreas. CyberKnife radiosurgery can provide rapid durable palliation in patients with bone, spine and liver metastases. It may be the only alternative for patients who have suffered local recurrence in spite of previous surgery and/or radiation therapy. In many instances, CyberKnife allows treatment for patients who are simply untreatable in the past.

A CyberKnife is no more a traditional linear accelerator than a GammaKnife is a cobalt machine and I fear that this misconception, if it persists, will deny our patients access to this new and exciting technology. As noted, a radiosurgery program attracts new patients that otherwise would not be treated and therefore, at least initially has no effect on the utilization of existing linear accelerators. As noted above, it may actually increase utilization in the future. Therefore, it seems unreasonable for an institution who can demonstrate the need for and the means to provide stereotactic radiosurgery to have to wait until there is an allocation for an accelerator in their area. Similarly, it also seems unreasonable to require an institution with fully utilized linear accelerators to decommission and relinquish the CON for one of their machines in order to acquire a stereotactic radiosurgery system in a timely fashion since this would inevitably result in over utilization of their remaining machines. This scenario could be a nightmare for all of us!

We believe that our application for CyberKnife demonstrates a need for stereotactic radiosurgery in our area as well as our ability to provide this service in an optimal fashion. While there are other methods of delivering stereotactic radiosurgery, we feel that CyberKnife is unique and the best solution for our patient population. Different institutions have different needs and may decide that GammaKnife, Tomotherapy or a modified all-purpose accelerator is best for them. We would not presume to select which technology is best for them or interfere with their ability to obtain a proper CON.

In summary, we believe that dedicated stereotactic radiosurgery systems such as CyberKnife should be placed in a special category and not considered replacement for standard linear accelerators. This would facilitate the orderly, controlled growth of stereotactic radiosurgery in North Carolina and ensure that our patients continue to have optimal access to oncology services.

Sincerely,

J. Hugh Bryan, MD
Medical Director
Radiation Oncology

SINAI HOSPITAL
a LifeBridge Health center

Department of Radiation Oncology
Sinai Hospital of Baltimore
Mt. Pleasant Building
2401 West Belvedere Avenue
Baltimore, MD 21215

June 25, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Facility Services
2714 Mail Service Center
Raleigh NC 27699-2714

RE: Special Need Determination for CyberKnife, Cape Fear Valley Health System

Dear Mr. Elkins:

I am writing to you in my capacity as chief of Radiation Oncology at Sinai Hospital of Baltimore. We provide standard Radiation Oncology services, both 2-dimensional Radiation Therapy and its immediate successor, 3-dimensional conformal radiation therapy (3D-CRT), and the two subsequent upgrades, Intensity Modulated Radiation Therapy (IMRT), and Image-Guided Radiation Therapy (IGRT). In April of 2003 we added Stereotactic Radiosurgery (SRS) to our practice in the form of the CyberKnife. Since then we have treated over 1000 with the CyberKnife, and in January of this year we started operations with our second CyberKnife, so great has the demand for it been. Unlike the aforementioned modes of pure Radiation Oncology, SRS is really a hybrid of radiation and surgery. Here, multiple pinpoint precise individual beams of irradiation are directed to a target, delivering doses far in excess of what can be done with any of the available modalities of standard irradiation, with the aim of ablating the tumor. SRS is truly "surgery without the scalpel"—it takes its lineage from the traditional neurosurgical/brain-only applications as provided by Gamma Knife, but with the crucial differences that it does not require that the patient be rigidly immobilized, and that it can treat lesions anywhere in the body. At our center we have already treated over 60 cases of medically inoperable lung cancers, and we presently have the largest series of stereotactically treated unresectable pancreatic cancers in the world!

Almost all Radiation Oncology departments today have traditional linear accelerators with IMRT/IGRT capacity, which allow for better treatment than older methods of therapy for cases where the tumor exists close to critical structures. But these systems do not and can not do true radiosurgery.

Stereotactic radiosurgery differs from these other techniques in several crucial ways:

1. Only the gross tumor is treated, with no attempt to treat the surrounding soft tissues and/or the draining lymph nodes, which may or may not contain microscopic tumor.

2. Little or no margin around the tumor is added to allow for day-to-day set-up variations or uncertainties, even without rigid immobilization, because,....

3. The system "knows" in real time where the patient and the tumor are located in all three dimensions and adjusts accordingly. Unlike the situation with IGRT, wherein imaging allows for precise day-to-day setup **before the beam is turned on**, this is true image guidance and artificial intelligence technology. Incredibly high doses of irradiation are delivered with pinpoint precision even to tumors that constantly move with respiration, in patients who move randomly and intermittently, with a margin of error of at most 1-2 millimeters!

4. Courses of treatment are administered over one to five fractions, not over several weeks, as is the case with standard Radiation Oncology.

SRS is not an alternative to radiation but to surgery. The paradigm here is that is that it is the surgeon who determines that whereas ideally the patient would be taken to the O.R., surgery is precluded because **the patient is medically inoperable** (e.g. severe COPD or coronary artery disease), and/or **the tumor is surgically unresectable** (e.g. it is encasing major vessels, or the region has already undergone maximum prior surgery or radiation). We recently looked back at all our CyberKnife cases, and found that virtually **none** of them could be treated with the available technology of pure Radiation Oncology (2D, 3D, IMRT or IGRT).

I would respectfully submit that dedicated SRS systems such as the CyberKnife should be separately accounted for in North Carolina for radiation therapy systems. These units are **not** replacements for standard linear accelerators, but rather, an entirely new modality, a hybrid of radiation and surgery, which provide

an alternative to surgery for patients who heretofore had simply run out of options.

Sincerely yours,

Mark J. Brenner, M.D., FACR
Chairman, Department of Radiation Oncology
Sinai Hospital of Baltimore
MJB/jmb

Southwest Radiation Oncology

June 23, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Facility Services
2714 Mail Service Center
Raleigh NC 27699-2714

RE: Special Need Determination for CyberKnife, Cape Fear Valley Health System

Southwest Radiation Oncology is an Oklahoma provider of Radiation Oncology services. These services include devices that can provide radiation therapy (RT), Intensity Modulated Radiation Therapy (IMRT), and Image-Guided Radiation Therapy (IGRT). In 2003, we investigated adding a Stereotactic Radiosurgery (SRS) Program to our practice. Our research indicated that SRS has evolved from the traditional neurosurgical/brain-only applications as provided by Gamma Knife or similar devices into a treatment option for lesions anywhere in the body. Before adding SRS to our practice we investigated thoroughly the impact an SRS program would have on our existing radiation therapy programs, our patients, and our community.

Many centers have traditional linear accelerators that used advanced technology for enhanced patient treatment, such as intensity modulated radiation therapy and/or image guided radiation therapy. Although these allow for better treatment than older methods of therapy for cases where the tumor exists close to critical structures, they are technologically and clinically distinct from radiosurgery. Stereotactic radiosurgery (SRS) differs from these other techniques in several ways:

1. Patients are treated in 1-5 fractions, not several weeks.
2. The identifiable tumor is treated, not areas at risk.
3. Little or no margin around the tumor is added to account for set-up uncertainties.
4. Image guidance is used daily.

SRS is generally used in two situations:

1. The patient would ordinarily be treated with surgery, but is not medically fit for such surgical intervention.
2. The problem is one for which surgery is impossible or inadvisable and standard radiation techniques have a high risk of resulting in significant injury.

SRS can sometimes be performed by traditional linear accelerators using special modifications, but is probably best performed by dedicated systems such as the CyberKnife. The CyberKnife also has the advantage of allowing motion tracking for tumors that move with respiration, and is the only system capable of such tracking.

For all these reasons, dedicated SRS systems such as the CyberKnife should separately accounted for in the planning of the state of North Carolina for radiation therapy systems. These units are not replacements for standard linear accelerators. It would be anticipated that the number of such systems would be far lower than the number of standard accelerators, but additional linear accelerators will not replace these systems.

Sincerely,

Clinton A. Medbery, III, M.D.
President
Southwest Radiation Oncology

Clinton A. Medbery III, M.D.
[illegible]

Astrid E. Morrison, M.D.
[illegible]

Marianne M. Young, M.D.
[illegible]

Frank C. Lowe Cancer Institute
1211 North Dewey
Oklahoma City, Oklahoma
73102

Main Number: 405.272.7311
Fax Number: 405.272.6962
After Hrs. Number: 405.272.7311

CUMBERLAND COUNTY

BOARD OF COMMISSIONERS
5th Floor, New Courthouse • P.O. Box 1829 • Fayetteville, North Carolina 28302-1829
910 678-7771 • Fax: 910 678-7770

July 27, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714.

Dear Mr. Elkins:

I am writing to support Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. I feel that the best possible healthcare and health technology should be available for our citizens. I believe that if Cape Fear Valley Health System replaces one of its fully-utilized linear accelerators, it will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents.

I am convinced that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery. It doesn't seem fair that areas with fewer capacity constraints should have better access to SRS/SRT services than other areas in North Carolina. For Cape Fear Valley, along with the residents of Area 18, to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable.

Your consideration to this request is appreciated.

Sincerely,

Ed Melvin

Ed Melvin
Commissioner

CUMBERLAND COUNTY

BOARD OF COMMISSIONERS
5th Floor, New Courthouse • PO Box 1829 • Fayetteville, North Carolina 28302-1829
(910) 678-7771 • Fax: (910) 678-7770

July 27, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

Please accept this letter as my support of Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. The health system is convinced that replacing one of its fully-utilized linear accelerators will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents.

For Cape Fear Valley, along with the residents of Area 18, to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced). I am convinced that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery.

I am hopeful that you will be convinced by the reasonable rationale submitted by Cape Fear Valley Health System that a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18 is warranted and has

merit. As a long time resident and member of the Cumberland County Board of Commissioners, I want the best possible healthcare and health technology available for me as well as the citizens I represent. Thank you for your consideration of this request.

Sincerely,

Billy R. King

Billy R. King
Commissioner

/mc

CUMBERLAND COUNTY

BOARD OF COMMISSIONERS
5th Floor, New Courthouse • PO Box 1829 • Fayetteville, North Carolina 28302-1829
(910) 678-7771 • Fax: (910) 678-7770

July 27, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

I support Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. I feel that the best possible healthcare and health technology should be available for our citizens.

For Cape Fear Valley, along with the residents of Area 18, to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced).

I would appreciate your consideration in granting the request for the need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18.

Sincerely,

Jeannette Council

Jeannette Council
Commissioner

/ mc

JAMES E. MARTIN
County Manager

JUANITA PILGRIM
Deputy County Manager

CLIFF SPILLER
Assistant County Manager

AMY H. CANNON
Assistant County Manager

CUMBERLAND COUNTY

OFFICE OF THE COUNTY MANAGER
5th Floor, New Courthouse • PO Box 1829 • Suite 512 • Fayetteville, North Carolina 28302-1829
910-678-7723 • 910-678-7726 • Fax: 910-678-7717

July 27, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

Please accept this letter in support of Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. I believe that if Cape Fear Valley Health System replaces one of its fully-utilized linear accelerators, it will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents. I feel that the best possible healthcare and health technology should be available for our citizens.

I am convinced that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery. It doesn't seem fair that areas with fewer capacity constraints should have better access to SRS/SRT services than other areas in North Carolina. For Cape Fear Valley, along with the residents of Area 18, to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced).

I would appreciate your favorable consideration of the request for the need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18.

Sincerely,

James Martin
County Manager

CUMBERLAND COUNTY

BOARD OF COMMISSIONERS
5th Floor, New Courthouse • P.O. Box 1829 • Fayetteville, North Carolina 28302-1829
910.678-7771 • Fax: 910.678-7770

July 27, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

This letter is written in support of Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. I agree with Cape Fear Valley Health System that replacing one of its fully-utilized linear accelerators will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents. As a long-time resident and member of the Cumberland County Board of Commissioners, I want the best possible healthcare and health technology available for the citizens of Cumberland County.

It doesn't seem fair that areas with fewer capacity constraints should have better access to SRS/SRT services than other areas in North Carolina. For Cape Fear Valley along with the residents of Area 18 to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced). I am convinced that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery.

I am hopeful that you will agree that a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18 is warranted and has merit. Thank you for your consideration of this request.

Sincerely,

J. Breeden Blackwell

J. Breeden Blackwell
Vice-Chairman

/mc

CUMBERLAND COUNTY

BOARD OF COMMISSIONERS
5th Floor, New Courthouse • P.O. Box 1829 • Fayetteville, North Carolina 28302-1829
910 678-7771 • Fax: 910 678-7770

July 27, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

Please know that I am in support of Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. The health system is convinced that replacing one of its fully-utilized linear accelerators will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents. As a long time resident and member of the Cumberland County Board of Commissioners, I want the best possible healthcare and health technology available for me as well as the citizens I represent.

For Cape Fear Valley, along with the residents of Area 18, to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced). I am convinced that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery. It doesn't seem fair that areas with fewer capacity constraints should have better access to SRS/SRT services than other areas in North Carolina.

I am hopeful that you will be convinced by the reasonable rationale submitted by Cape Fear Valley Health System that a need adjustment to the State Medical Facilities Plan (SMFP) to add

the need for a CyberKnife Stereotactic Radiosurgery System in Area 18 is warranted and has merit. Thank you for your consideration of my and their request.

Sincerely,

Kenneth S. Edge
Chairman

/mc

Health & Healing
2623 Westchester Drive
Fayetteville, NC 28303-5227

July 31, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

I am writing on behalf of Cape Fear Valley Health System (CFVHS) to request your support in adjusting the definition of "need" for the system. As a retired MCH nursing consultant with the Division of Health Services, I support the need for your agency to oversee allocations of "high- dollar" medical equipment in our State. In my former life, I found that the Cumberland-Bladen-Robeson-Sampson geographic area was always trying to play catch-up with the rest of North Carolina in obtaining the equipment needed to provide appropriate services to the population in three of the geographically largest counties of our State. Because we are still trying to catch up on equipment and because of the geographic size of the area, we needed the Linear Accelerator placed at the Health Pavilion North campus of CFVHS to meet the needs of our citizens.

Today, we are also in a new era for Cape Fear Valley Health System. In addition to the more routine services found in a large medical center, we are ready to provide cutting-edge technology. We are also attempting to reach out to the surrounding counties to meet the needs of the medically underserved population in this large region as well as that of Cumberland County. In addition, Ft. Bragg is one of the bases that is in the process of enlarging under the Base Realignment and Closure (BRAC) recommendations; and, Ft. Bragg is a base of choice for soldiers who have exceptional family member needs. Our neurosurgeons serve both soldiers and their dependents. It is anticipated that we may also see the need for CyberKnife Stereotactic Radiosurgery in this younger population.

Last November we requested approval for the CyberKnife. Please see my attached letter of support dated 11/09/06. Nothing has changed, except my friend, the cancer patient who could have used this type of surgery, has died. We still have the support of the multiple physician practices and people in need. While we still need and utilize the Linear Accelerator when it is appropriate, we also have a need and responsibility to provide cutting-edge technology to the population of Southeastern North Carolina which the CyberKnife Stereotactic Radiosurgery system will provide. While this is a large geographic area, Fayetteville is easily accessible to all major areas in the surrounding

counties. We hope you will consider the placement of the CyberKnife at Cape Fear Valley Health System to meet your objectives: to promote and encourage cost-effective quality health care services and to expand the health care services to an area that is medically underserved. With your support, we, the trustees of Cape Fear Valley Health System, are willing to take on this responsibility.

Thank you in advance for expanding your consideration to enable us to meet the needs of the population of southeastern North Carolina.

Sincerely,

Mary Buie

Mary Buie, RN, MPH, Secretary/Treasurer
Cape Fear Valley Health System Board of Trustees

Cc: Linda Clark
Joyce Korzen

G

John R. Griffin, Jr.
2481 Themesford Road
Fayetteville, NC 28311
****

July 31, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

Please know that I am in support of Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. The health system is convinced that replacing one of its fully-utilized linear accelerators will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents. As a long time resident of Cumberland County, former Superintendent of the Cumberland County School System and a current member of the Board of Trustees, I know that we need the best possible healthcare and health technology available for the citizens of Cumberland County and this region.

For Cape Fear Valley along with the residents of Area 18 to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced). I am convinced that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery. It doesn't seem fair that areas with fewer capacity constraints should have better access to SRS/SRT services than other areas in North Carolina.

Hopefully, you will be convinced by the reasonable rationale submitted by Cape Fear Valley Health System that a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18 is warranted and has merit. Thank you for your sincere consideration of Cape Fear Valley's request.

Sincerely,

John R. Griffin, Jr.
First Vice Chairman, Board of Trustees

BCH
BLADEN COUNTY HOSPITAL

July 31, 2007

Mr. Tom Elkins, Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins,

On behalf of Bladen County Hospital and the citizens of Bladen County, I am writing to support the application submitted by Cape Fear Valley Health System for an additional linear acceleration dedicated to Cyberknife Technology.

It is our understanding that this minimally invasive technology is rapidly becoming standard of practice throughout the state for the treatment of cancer, and we support the efforts of Cape Fear Valley Health System to bring Cyberknife Stereotactic Radiosurgery to the citizens of Southeastern North Carolina.

This technology requires the dedication of a linear accelerator and we believe that the advancements in medicine should be considered in adjusting need determination for linear accelerators in the State's Medical Facility Plan. Recognizing that the regional demand for the existing linear accelerators exceeds capacity further compels us to support this request.

In summary, Bladen County Hospital, as a primary care provider in a contiguous county, supports Cape Fear Valley Health System's request to appropriately adjust the need determination as stated in the State Medical Facility Plan to recognize the requirements for Cyberknife Stereotactic Radiosurgery in area 18.

Respectfully submitted,

David J. Masterson, CEO
Bladen County Hospital

Cc: Lynda Clark, VP Professional Services
CFVHS

North Carolina General Assembly
House of Representatives
Legislative Building
Raleigh 27601-1096

Former / Retired
REPRESENTATIVE JOHN W. "BILL" HURLEY
18TH DISTRICT
OFFICE ADDRESS 2215 LEGISLATIVE BUILDING
RALEIGH, NC 27601-1096
TELEPHONE (919) 733-5601
(919) 733-2599 FAX
HOME ADDRESS 313 KIRKWOOD DRIVE
FAYETTEVILLE, NC 28303-4985
(910) 868-4078
BUS. ADDRESS PO BOX 714
FAYETTEVILLE, NC 28302
(910) 483-6210

COMMITTEES
INSURANCE, CHAIR
MILITARY, VETERANS & INDIAN AFFAIRS, CHAIR
CONGRESSIONAL REDISTRICTING
ETHICS
FINANCE
LOCAL GOVERNMENT II
PUBLIC UTILITIES

July 31, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

Recently, I received information from Cape Fear Valley Medical Health System (CFVHS) advising that a request for a CyberKnife Stereotactic Radiosurgery System was denied by your section.

I would like to request that due to the significance of the geographic location and the population in our region you reverse this decision, make an adjustment to need determination, and grant this certification of need for the CyberKnife Stereotactic Radiosurgery System. Our military base alone will increase by 2,100 people before the year 2010. As you know, our area is still the predominate metro-hub in southeastern North Carolina, and I feel the requested system would be of great value to the citizens of Cumberland and surrounding counties.

Your consideration of this request is appreciated, and if you have any questions or I can be of further service, please contact me.

Sincerely,

John W. "Bill" Hurley

JWHm

Technology and Equipment Committee Meeting

August 29, 2007

Radiation Oncology Services - Linear Accelerators

Comments Related To

Linac Petition-2: Cape Fear Valley Health System

COUNTY *of* CUMBERLAND

Board of County Commissioners

August 2, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins,

I am writing this letter on behalf of Cape Fear Valley Health System's request for an adjustment to the need determination for the development of a CyberKnife Stereotactic Radiosurgery system in the 2008 Sate Medical Facilities plan (SMFP) in linear accelerator area 18 (Area 18).

As an Otolaryngologist and a member of the Cumberland County Board of Commissioners, I strongly support this request for the requested adjustment of the SMFP. It is my understanding that the previous application for the CyberKnife was denied because the population per accelerator in Area 18 did not exceed 120,000 persons and only 12% of patients treated here resided outside Area 18. There are two issues here that must be considered. As you may very well know, with the recent base realignment, there will be substantial growth in the Cumberland County and surrounding region over the next 3-4 years. As a county commissioner, I have been briefed as county commissioners that up to 40,000 people will be moving into Cumberland County and surrounding counties because of the expected growth of Fort Bragg. There will, therefore, be increased need for this type of treatment for the military and their dependents as well. In addition, there is an ever increasing number of specialists in Cumberland County and surrounding areas who will be referring patients for this technology. I strongly believe in my own specialty and in others that this type of new technology will be a strong draw for patients to have access to and utilization of this new technology.

It is also impractical for Cape Fear Valley to replace an existing linear accelerator with the CyberKnife technology. Our utilization of our current linear accelerators already exceeds the state requirement for an additional

accelerator. By merely substituting the CyberKnife for a linear accelerator, it will delay needed radiation therapy to patients requiring that specific methodology rather than the treatment offered by the CyberKnife technology.

Finally, I am aware that CyberKnife services are available in Asheville and in Concord. In addition, UNC and East Carolina University have either been approved or have applied for this technology. For many years, residents of Cumberland and surrounding counties have been delayed in obtaining needed approvals for services to be provided to our residents. This is a low wealth area and our patients deserve and need access to the latest technology in the treatment of their malignancies. It is impractical for many of these low income patients to travel to UNC or, as I believe likely, to one of the facilities in Wake County or to Duke University which will ultimately be approved. It is entirely appropriate for the SMFP to be adjusted to allow this technology to be placed centrally in southeastern North Carolina and to provide service in this area. As previously noted, Cumberland County and the Cape Fear Valley Health System will be rapidly growing and, for the first time in my 27 years here, we are beginning to see an influx of new, well-trained physicians in many specialties. Although those persons living in the triangle have had the privilege of easy access to specialty care for many years, that has not been true in Cumberland County and in southeastern North Carolina. It is time to allow Cape Fear Valley Health System to provide this needed service as soon as possible.

If I may supply additional information, please do not hesitate to contact me.

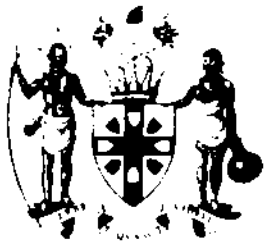
Sincerely,

John T. Henley, Jr., MD
JTH/cwc

SENATE OF NORTH CAROLINA

SENATOR TONY RAND
19TH DISTRICT

LEGISLATIVE OFFICE BUILDING
300 N. SALISBURY STREET
RALEIGH, N.C. 27603-5925
919.733.9892
919.715.8346 FAX
tonyr@ncleg.net



MAJORITY LEADER

CHAIRMAN,
RULES AND OPERATIONS OF THE SENATE
CHAIRMAN,
EMPLOYEE HOSPITAL AND MEDICAL BENEFITS
VICE CHAIRMAN,
COMMERCE

August 2, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

This letter is written in support of Cape Fear Valley Health System's request for an adjustment to need determination for the development of a CyberKnife Stereotactic Radiosurgery System in the 2008 State Medical Facilities Plan (SMFP) in linear accelerator Area 18.

Cape Fear Valley Health System's linear accelerators already exceed the capacity threshold, so replacing an existing linear accelerator with a CyberKnife Stereotactic Radiosurgery System is not an option for Area 18. Area 18 has a large population of over 535,000 people. This is more than adequate to support a dedicated SRS/SRT service.

Cape Fear Valley Health System has been providing quality healthcare for the residents of Cumberland County and surrounding communities since 1956. The additional services would allow them to provide the best available technology to treat patients with devastating illnesses. I would appreciate your consideration of this request.

Very truly yours,

Anthony E. Rand

AER:jt

2014 LITHO PLACE, FAYETTEVILLE, NORTH CAROLINA 28304
BUSINESS – 910.222-8006 EXT. 245 HOME – 910.864-0550

BCH
BLADEN COUNTY HOSPITAL

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AUG 04 2007
Medical Facilities
Planning Section

July 31, 2007

Mr. Tom Elkins, Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins,

On behalf of Bladen County Hospital and the citizens of Bladen County, I am writing to support the application submitted by Cape Fear Valley Health System for an additional linear acceleration dedicated to Cyberknife Technology.

It is our understanding that this minimally invasive technology is rapidly becoming standard of practice throughout the state for the treatment of cancer, and we support the efforts of Cape Fear Valley Health System to bring Cyberknife Stereotactic Radiosurgery to the citizens of Southeastern North Carolina.

This technology requires the dedication of a linear accelerator and we believe that the advancements in medicine should be considered in adjusting need determination for linear accelerators in the State's Medical Facility Plan. Recognizing that the regional demand for the existing linear accelerators exceeds capacity further compels us to support this request.

In summary, Bladen County Hospital, as a primary care provider in a contiguous county, supports Cape Fear Valley Health System's request to appropriately adjust the need determination as stated in the State Medical Facility Plan to recognize the requirements for Cyberknife Stereotactic Radiosurgery in area 18.

Respectfully submitted,

David J. Masterson, CEO
Bladen County Hospital

Cc: Lynda Clark, VP Professional Services
CFVHS

Buie, Norman & Co., P.A.
CERTIFIED PUBLIC ACCOUNTANTS

2294 McGill Drive
Post Office Box 87047
Fayetteville, NC 28304-7047
www.buienorman.com

John G. Buie, Jr., CPA
Robert D. Norman, CPA
Larry L. Bass, Jr., CPA

Tel: (910) 484-0145
Fax: (910) 485-4524

Member AICPA, NCACPA

July 31, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714.

Dear Mr. Elkins:

Cape Fear Valley Health System has submitted a request to the Division of Health Service Regulation petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18 and I am extremely supportive of this request. The health system is convinced that replacing one of its fully-utilized linear accelerators will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents. As a long time resident of Cumberland County and a current member of the Board of Trustees, I know that we need and are expected to provided the best possible healthcare and health technology for the citizens of Cumberland County and this region.

For the residents of Area 18 along with Cape Fear Valley to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced). I am certain that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery. It doesn't seem fair that areas with fewer capacity constraints should have better access to SRS/SRT services than other areas in North Carolina.

I am convinced that after review of the reasonable rationale submitted by Cape Fear Valley Health System that a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18 is warranted, has merit and should be approved. Thank you for your sincere consideration of my support and Cape Fear Valley's request.

Sincerely,

John G. Buie, Jr., CPA
President Cape Fear Valley Health Foundation Board of Trustees
Member Cape Fear Valley Health System Board of Trustees

North Carolina General Assembly
House of Representatives
Legislative Building
Raleigh 27601-1096

Former / Retired

REPRESENTATIVE JOHN W. "BILL" HURLEY
18TH DISTRICT
OFFICE ADDRESS 2215 LEGISLATIVE BUILDING
RALEIGH, NC 27601-1096
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COMMITTEES
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July 31, 2007

DFS Health Planning
RECEIVED
AUG 02 2007
Medical Facilities Planning Section

Mr. Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

Recently, I received information from Cape Fear Valley Medical Health System (CFVHS) advising that a request for a CyberKnife Stereotactic Radiosurgery System was denied by your section.

I would like to request that due to the significance of the geographic location and the population in our region you reverse this decision, make an adjustment to need determination, and grant this certification of need for the CyberKnife Stereotactic Radiosurgery System. Our military base alone will increase by 2,100 people before the year 2010. As you know, our area is still the predominate metro-hub in southeastern North Carolina, and I feel the requested system would be of great value to the citizens of Cumberland and surrounding counties.

Your consideration of this request is appreciated, and if you have any questions or I can be of further service, please contact me.

Sincerely,

John W. "Bill" Hurley

JWHm

ROBIN HAYES
8TH DISTRICT, NORTH CAROLINA

130 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
202-225-3715
FAX: (202) 225-4036
www.house.gov/hayes

COMMITTEES
COMMITTEE ON ARMED SERVICES
COMMITTEE ON AGRICULTURE
COMMITTEE ON TRANSPORTATION AND INFRASTRUCTURE

DISTRICT OFFICES
147 UNION STREET SOUTH
CONCORD, NC 28025
704-786-1612
FAX: 704-782-1004

230 EAST FRANKLIN STREET
ROCKINGHAM, NC 28379
910-997-2070
FAX: 910-997-2987

TOLL FREE IN NC
888-[illegible]

Congress of the United States
House of Representatives

Washington, DC 20515–3308
August 2, 2007

DFS Health Planning
RECEIVED
AUG 09 2007
Medical Facilities
Planning Section

Mr. Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

I am writing to you on behalf of Cape Fear Valley Health System in Fayetteville, North Carolina. CFVHS has brought to my attention their concern over a need adjustment to the State Medical Facilities plan (SMFP) to add a Cyperknife Stereotactic Radiosurgery System in Area 18, as well as, their intent to file a petition for a need adjustment to The Division of Health Service Regulation in July 2007.

CFVHS has expressed to me their belief that replacing one of its fully-utilized linear accelerators will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents.

I thank you for your attention to this issue, and I ask that you give their request your full consideration.

Sincerely,

Robin Hayes

Robin Hayes

HAROLD L. GODWIN, M.D.
1813 Lakeshore Drive
Fayetteville, NC 28305-5240
Phone: (910) 484-8311
Fax: (910) 609-6714
E-mail: hlninagodwin@webtv.net

August 8, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

Please know that I am in support of Cape Fear Valley Health System's request in petitioning for a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. The health system is convinced that replacing one of its fully-utilized linear accelerators will not best serve patients and that area residents should have access to leading edge technologies accessible to other North Carolina residents. As a long time resident of Cumberland County, former practicing Internal Medicine physician, former CEO of the Duke Southern Area Health Education Center, and a strong supporter of healthcare in my community, I know that we need the best possible healthcare and health technology available for the citizens of Cumberland County and this region.

For Cape Fear Valley along with the residents of Area 18 to possibly not be able to gain access to CyberKnife technology considering a) the current linear accelerator methodology, b) the CON section's interpretation that the SMFP demonstrate a need for an accelerator before CyberKnife equipment is acquired, and c) the current utilization rate of Area 18's linear accelerators, in my opinion is unreasonable. Moreover, when need is identified in future SMFPs, Cape Fear Valley or other Area 18 providers may be compelled to add an EBRT linear accelerator given the capacity constraints (surely to be created if one of the current accelerators is replaced). I am convinced that Area 18 is truly in a unique position relative to its large population and its inability to replace a highly utilized linear accelerator with CyberKnife equipment for stereotactic radiosurgery. It doesn't seem fair that areas with fewer capacity constraints should have better access to SRS/SRT services than other areas in North Carolina.

Hopefully, you will be convinced by the reasonable rationale submitted by Cape Fear Valley Health System that a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18 is warranted and has merit. Thank you for your sincere consideration of Cape Fear Valley's request.

Sincerely,

Harold L. Godwin, M.D.

BURKHEAD DEVANE inc.
Label Specialists
www.burkheaddevane.com
407 Cumberland Street
Fayetteville, NC 28301
Phone: 800.633.2450
Fax: 910.483.4754
ISO9001:2000

July 31, 2007

Tom Elkins
Medical Facilities Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

I am writing this letter in support of Cape Fear Valley Health Systems being allowed to have a cyber knife.

I don't know anything about a cyber knife but I do know about the suffering of cancer. I have had prostate cancer for 15 years. Twice I had to take radiation and to date I am taking chemo therapy for bone cancer. In January of this year we discovered that my wife had cancer and had to have her uterus removed in February. In March we found that she had breast cancer, had surgery and then had to have radiation. Because of all of this I have seen cancer patients for 15 years and I know how severe their suffering is and I know that the people of Cape Fear Valley Cancer Center are not only professional, but are the most caring and kind people that you could find anywhere.

I realize that in your job money is more important to you than suffering; however, if you get cancer you'll find out that money becomes very unimportant – you want the people taking care of you to have the best and latest equipment.

The Fayetteville area services over a half million population. Mr. Elkins, Cape Fear Valley Hospital Systems and we cancer patients need and deserve the equipment for the cyber knife.

Sincerely,

James D. DeVane, III

cc: J.Korzen, L. Clark

Health & Healing
2623 Westchester Drive
Fayetteville, NC 28303-5227

July 31, 2007

Mr. Tom Elkins
Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Mr. Elkins:

I am writing on behalf of Cape Fear Valley Health System (CFVHS) to request your support in adjusting the definition of "need" for the system. As a retired MCH nursing consultant with the Division of Health Services, I support the need for your agency to oversee allocations of "high- dollar" medical equipment in our State. In my former life, I found that the Cumberland-Bladen-Robeson-Sampson geographic area was always trying to play catch-up with the rest of North Carolina in obtaining the equipment needed to provide appropriate services to the population in three of the geographically largest counties of our State. Because we are still trying to catch up on equipment and because of the geographic size of the area, we needed the Linear Acceleator placed at the Health Pavilion North campus of CFVHS to meet the needs of our citizens.

Today, we are also in a new era for Cape Fear Valley Health System. In addition to the more routine services found in a large medical center, we are ready to provide cutting-edge technology. We are also attempting to reach out to the surrounding counties to meet the needs of the medically underserved population in this large region as well as that of Cumberland County. In addition, Ft. Bragg is one of the bases that is in the process of enlarging under the Base Realignment and Closure (BRAC) recommendations; and, Ft. Bragg is a base of choice for soldiers who have exceptional family member needs. Our neurosurgeons serve both soldiers and their dependents. It is anticipated that we may also see the need for CyberKnife Stereotactic Radiosurgery in this younger population.

Last November we requested approval for the CyberKnife. Please see my attached letter of support dated 11/09/06. Nothing has changed, except my friend, the cancer patient who could have used this type of surgery, has died. We still have the support of the multiple physician practices and people in need. While we still need and utilize the Linear Acceleator when it is appropriate, we also have a need and responsibility to provide cutting-edge technology to the population of Southeastern North Carolina which the CyberKnife Stereotactic Radiosurgery system will provide. While this is a large geographic area, Fayetteville is easily accessible to all major areas in the surrounding

counties. We hope you will consider the placement of the CyberKnife at Cape Fear Valley Health System to meet your objectives: to promote and encourage cost-effective quality health care services and to expand the health care services to an area that is medically underserved. With your support, we, the trustees of Cape Fear Valley Health System, are willing to take on this responsibility.

Thank you in advance for expanding your consideration to enable us to meet the needs of the population of southeastern North Carolina.

Sincerely,

Mary Buie

Mary Buie, RN, MPH, Secretary/Treasurer
Cape Fear Valley Health System Board of Trustees

Cc: Lynda Clark
Joyce Korzen

Health & Healing
2623 Westchester Drive
Fayetteville, NC 28303-5227

November 9, 2006

Ms. Lynda B. Clark
Vice President, Professional Services
Cape Fear Valley Health System
1638 Owen Drive
Fayetteville, NC 28302-2000

RE: Support of CON request for CyberKnife Stereotactic Radiosurgery System

Dear Lynda,

I am writing this letter to support Cape Fear Valley Health System's certificate of need application to expand its ability to provide state-of-the-art-services to the citizens of Cumberland County and southeastern North Carolina.

I was truly excited when I heard the presentation you made at a board of trustees committee meeting. Your presentation was great, but the enthusiasm of Dr. Hugh Bryan, the radiation oncologist was invigorating. I have also talked with Drs. Carol Wadon and Bruce Jaufmann, two great neurosurgeons on staff at Cape Fear Valley and they, too, are excited about the ability they will have to perform finite surgery.

I personally know several people who have had cancer for several years. One is now dealing with metastasis to the lung in a location too close to the spinal column for surgery using our present technical capability. The CyberKnife System would be God-sent for her. I look forward to being able to help people, like my friend, with this new capability. This has been presented to the Cape Fear Valley Health System Board of Trustees,who looks closely at the cost of new technology in relation to the need of our citizens. We overwhelmingly recommended that the CON to pursued.

Cape Fear Valley Health System has the backing of the Board of Trustees, the excitement and commitment of multiple physician specialties and a population in need of this service.

I wish to thank the CON Section for consideration of this request and I strongly encourage the CON Section to approve the Cyberknife Stereotactic Radiosurgery System for Cape Fear Valley.

Sincerely,

Mary G. Buie, RN, MPH, Trustee
Cape Fear Valley Health System

player, inc.
SINCE 1938

P.O. DRAWER 27 / FAYETTEVILLE, NC 28302 / 910.868.2121 / FAX 910.868.2126 / E-MAIL player@playerinc.net

August 1, 2007

Mr. Tom Elkins, Medical Planning Section
The Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Petition for a need adjustment to the SMFP to add CyberKnife
Cape Fear Valley Health System

Dear Mr. Elkins:

It is my understanding that Cape Fear Valley Health System is requesting a need adjustment to the State Medical Facilities Plan (SMFP) to add the need for a CyberKnife Stereotactic Radiosurgery System in Area 18. I certainly support this request.

Cumberland County, along with surrounding counties, is experiencing rapid growth. This is creating major needs important to the number of patients in this large area. This CyberKnife Stereotactic Radiosurgery System is needed to support the treatment needs of the patients and the physicians.

I encourage the Certificate of Need Section to adjust the need determination for development of a CyberKnife Stereotactic Radiosurgery System for our Health System and the citizens of Cumberland County and surrounding area.

Sincerely,

Richard L. Player III
2220 Bayview Drive
Fayetteville, NC 28305

Technology and Equipment Committee Meeting

August 29, 2007

Radiation Oncology Services - Linear Accelerators

Material Related To

Linac Petition-3: Rex Hospital

COMMENTS AND PETITION FOR CORRECTION TO THE INVENTORY

Petitioner:
Rex Hospital
4420 Lake Boone Trail
Raleigh, NC 27607

Represented by:
Rebekah Swain
Director, Strategic Planning
(919) 784-4483

Executive Summary:
Rex Hospital requests that the State Health Coordinating Council adjust the inventory of linear accelerators shown on pages 109 and 111 of the draft 2008 State Medical Facilities Plan to correct the omission of the Franklin Regional Cancer Treatment Center.

Background:
The petitioner, Rex Hospital, is located in Wake County and provides cancer treatment services in the Rex Cancer Center. The Rex Cancer Center was the first accredited comprehensive community cancer center in North Carolina, as designated by the American College of Surgeons. Rex provides radiation therapy services on four linear accelerators, all currently located on its main campus in western Raleigh.

Franklin Regional Cancer Treatment Center is located in Louisburg, Franklin County, NC. Franklin County, together with Wake and Harnett Counties, comprise linear accelerator Service Area 20 as shown in Table 9I, pages 112-114 of the draft 2008 State Medical Facilities Plan ("draft Plan").

Franklin Regional Cancer Treatment Center (FRCTC) began providing services on May 1, 2006, as shown in Exhibit A, an article from the Franklin Times dated July 7, 2006. The article states that the facility was to hold an open house on the following Tuesday, July 11, 2006.

In August 2006, CON Agency Analyst Michael McKillip wrote to FRCTC, requesting documentation of the purchase of the linear accelerator being used to provide radiation therapy services. In September 2006, Lee Whitman, acting as representative for FRCTC, responded to Mr. McKillip's inquiry by providing documentation that the linear accelerator and simulator were purchased below the $250,000 limit in July 2005, before the law changed in August 2005. The CON section has issued no response to this matter. FRCTC continues to treat patients each day on its linear accelerator.

Requested Change:
Rex Hospital respectfully requests that Franklin Regional Cancer Treatment Center be included in the inventory of radiation oncology service providers for Service Area 20. If this change is not made, the inventory will continue to be incorrect and misleading.

Thank you for the opportunity to review the draft Plan and provide our comments.

Exhibit 1

thefranklintimes.com

Presented by The Franklin Times

Search The Franklin Times

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My recent searches

You searched for "cancer treatment center"

results 1 through 25 of 916 sorted by releva
page 1 of 37 :: 1 | 2 | 3 | 4 | 5

Cancer Treatment Center improves quality of care (relevance: 100%, date: July 7, 2006)
Since May 1, the Franklin Regional Cancer Treatment Center has been providing state-of the-art care for patients in and around the county.
The center, located on Jolly Street in Louisburg, brings together chemotherapy and radiation treatment in one location.
?It?s a valuable new resource for local citizens,? said Paige McLaurin, the company?s property and office manager. ?Not only does it make it more convenient for the patients, but it also improves the quality of care by enhancing coordinating the efforts.?

2007 Relay for Life plans get going this Friday night (relevance: 57.4%, date Nov 14, 2006)
As the co-chair of the Franklin County Relay For Life, I would like to take this opportunit to express appreciation to the citizens of Franklin County for supporting the fight against cancer.

Relay for Life: fighting against cancer all year long (relevance: 54.6%, date: Apr 27, 2007)
As I reflect back on Friday night?s Relay For Life (April 20) and the people whose exister has been impacted through despair, loss, hope and victory, it brought back a sad, yet swe remembrance of my Uncle Jim, while suffering from the latter stages of lung cancer still making his way to a nearby Lizard?s Thicket restaurant and allowing me the chance to spend a couple of nights at his home on the outskirts of Columbia S.C., before I headed o to Florida;

RELAY FOR LIFE (relevance: 52.3%, date: Jan 12, 2007)
Variety show
?Famous? New Hope hot dogs, along with homemade french fries, will be sold at New H Christian Church on Saturday, Jan. 13, from 5 to 6 p.m., followed by a variety show at 6:3 p.m.
Proceeds will be donated to the American Cancer Society. Yard Sale
Rock Spring Baptist Church Relay For Life team will have a yard sale Saturday, Jan. 27 (7 a.m. - until), between Jeffrey?s and Annie Lee?s on Highway 39 South. All proceeds will benefit the American Cancer Society. Steak Dinner
Rock Spring Baptist Church Relay For Life team will be hosting a steak dinner Saturday,

Exhibit 1

Cancer Treatment Center improves quality of care

By CAREY JOHNSON, Times Staff Writer

GETTING READY. Assistants Wilma Hooker, left, and Jamie Jenkins, help a patient get ready for a radiation treatment
(Times photo by Carey Johnson)

Since May 1, the Franklin Regional Cancer Treatment Center has been providing state-of-the-art care for patients in and around the county.

The center, located on Jolly Street in Louisburg, brings together chemotherapy and radiation treatment in one location.

?It?s a valuable new resource for local citizens,? said Paige McLaurin, the company?s property and office manager. ?Not only does it make it more convenient for the patients, but it also improves the quality of care by enhancing coordinating the efforts.?

Her husband, Dr. Bob McLaurin Jr., agreed.

Two years ago, a Rocky Mount group of oncologists opened a satellite clinic in Franklin County but could only provide chemotherapy.

Cancer sufferers had to go elsewhere for radiation treatment.

?When they brought chemotherapy treatment here, that was a big step ... but a big element is radiation oncology,? Dr. McLaurin said. ?The two can work together.

?Until recently, (patients) had to go to Henderson, Raleigh or Rocky Mount to receive the radiation treatment.?

That?s because the key mechanism for radiation treatment ? a linear accelerator ? isn?t exactly cheap.

The device, which costs millions of dollars, delivers a uniform dose of high-energy X-ray to the region of the patient?s tumor.

The X-rays can destroy the cancer cells while sparing the surrounding normal tissue.

In the office, oncologists and other staff coordinate a course of care, using patient history, expertise, computer equipment and other devices to treat cancer.

Dr. McLaurin works in the office with Drs. Franciso Castillos and Daniel Crocker.

McLaurin, who?s lived in Wake County for 18 years, though, has been involved in designing and developing new cancer centers for over 20 years, including centers in Missouri and Pennsylvania.

His last four centers have been in North Carolina.

He said Franklin County was a destination spot for him.

?It has always been my goal to be able to develop a center in a small community where we can provide customized care for patients,? he said. ?This is the sixth center and hopefully will be the last.

?I?ve been working to try to get to this point to get into a small community and really participate with its members to try to develop center that would be valuable to all.

?It?s already been quite clear from hospital administrators to the citizens of the community to the Chamber of Commerce that everyone is very supportive of our being here and providing this service to the patients.?

The Franklin County Chamber of Commerce is hosting a ribbon cutting ceremony, set for noon on Tuesday at the center at 113 Jolly St.